IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

Applicants : D. Brumbach et al.

Serial No. : 10/802,712

Filed : March 17, 2003

For : SYSTEM AND METHOD FOR PROCESSING INFORMATION RELATED TO LABORATORY TESTS AND RESULTS

Examiner : Mary C. Baran

Art Unit : 2857

APPEAL BRIEF

May It Please The Honorable Board:

Appellants appeal the Final Rejection, dated January 12, 2006 of Claims 1 - 25 of the above-identified application. The fee of five hundred dollars ($500.00) for filing this Brief and any associated extension fee is to be charged to Deposit Account No. 19-2179. Enclosed is a single copy of this Brief.

Please charge any additional fee or credit any overpayment to the above-identified Deposit Account.

Appellants do not request an oral hearing.

I. REAL PARTY IN INTEREST

The real party in interest of Application Serial No. 10/802,712 is the Assignee of record:

Siemens Medical Solutions Health Services Corporation
51 Valley Stream Parkway
Malvern, PA 19355-1406

II. RELATED APPEALS AND INTERFERENCES

There are currently, and have been, no related Appeals or Interferences regarding Application Serial No. 10/802,712.

III. STATUS OF THE CLAIMS

Claims 1 - 25 are rejected and the rejection of claims 1 – 25 are appealed.

IV. STATUS OF AMENDMENTS

All amendments were entered and are reflected in the claims included in Appendix I.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 describes a system for processing information related to laboratory tests and results. An interface processor receives user entered data identifying a laboratory test result of a patient specimen culture (page 2, lines 31-32; Figure 1, 2). User entered data identifying an expected result of said laboratory test and data identifying a validation pre-condition are received (page 5, line 33 to page 6, line 2). A validation processor employs one or more user determined validation pre-conditions in comparing the laboratory test result with the expected test result (page 2, line 33-34; Figure 1, 4). A first failure condition is identified in response to the laboratory test result failing to match

the expected test result (page 2, line 34 to page 3, line 1). A result processor initiates generation of an alert message to a user indicating the first failure condition (page 3, lines 1-2; Figure 1, 6).

Dependent claim 2 includes the features of independent claim 1 along with the additional feature that the interface processor further receives user entered data identifying at least one further laboratory test result of the patient and user entered data identifying at least one further expected laboratory test result of the at least one further laboratory test result (page 5, lines 21-23; Figure 1). The validation processor compares the at least one further laboratory test result with the at least one further expected laboratory test result and identifies a second failure condition in response to the at least one further laboratory test result of the patient failing to match the at least one further expected laboratory test result (page 7, lines 5-7). The result processor initiates generation of an alert message to a user indicating the second failure condition (FIG 2, 224).

Dependent claim 3 includes the features of independent claim 1 along with the additional feature that the interface processor further receives user entered data identifying a plurality of validation pre-conditions for validating the laboratory test of the patient (page 5, lines 20-21; Figure 2, 200). The validation processor identifies a second failure condition when at least one of the plurality of validation pre-conditions are not satisfied (page 7, lines 5-7). The result processor initiates generation of an alert message to a user indicating the second failure condition (FIG 2, 224).

Dependent claim 4 includes the features of independent claim 1 along with the additional feature that the received user entered data identifying an expected result of the laboratory test comprises at least one of, (a) an identifier indicating a culture is resistant to

a test compound, (b) an identifier indicating a culture is sensitive to a test compound, (c) an identifier indicating a positive test result and (d) an identifier indicating a negative test result (page 11, lines 6-9; Figure 2, 212).

Dependent claim 5 includes the features of independent claim 1 along with the additional feature that the received user entered data identifying an expected result of the laboratory test comprises a quantity identifier indicating presence of an approximate quantity of microbes per unit area of a culture (page 11, lines 10-12; FIG 5C, 570).

Dependent claim 6 includes the features of independent claim 1 and claim 5 along with the additional feature that the quantity identifier identifiers a qualitative range of the quantity of microbes per unit area, including at least one of, (a) an identifier indicating "few" and (b) an identifier indicating "many" (page 11, lines 12-14; Figure 5c).

Dependent claim 8 includes the features of independent claim 1 along with the additional feature that the received user entered data identifying an expected result of the laboratory test identifies at least one of, (a) a count value of number of microbes present per unit area of a culture (page 11, lines 10-12), (b) a color of a microbe indicator, (c) a color change of a microbe indicator (page 9, lines 18-19).

Dependent claim 9 includes the features of independent claim 1 along with the additional feature that the received user entered data identifies a plurality of expected results of the laboratory test (page 5, lines 21-23; Figure 2, 232a). The validation processor compares a plurality of laboratory test results with the plurality of expected results and identifies a failure condition in response to a predetermined condition if at least

one of the plurality of laboratory test results fails to match a corresponding one of the plurality of expected results (page 7, lines 5-7; Figure 2, 234).

Dependent claim 10 includes the features of independent claim 1 along with the additional feature that the interface processor receives user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test (page 9, lines 23-25; Figure 1, 100 and 2). The validation processor compares an individual result of the plurality of expected test results with a corresponding individual laboratory test result of the plurality of test results and identifies a failure condition in response to the individual laboratory test result failing to match the corresponding expected test result (page 10, line 4 to page 11, line 2, Figure 2, 208, 234, 236). The result processor initiates generation of an alert message to a user indicating a failure condition of the individual test performed at a particular time stage of the different time stages (page 11, lines 4-5).

Dependent claim 11 includes the features of independent claim 1 along with the additional feature that the result processor initiates generation of an alert message to a user in response to occurrence of the failure condition (page 11, lines 4-5; Figure 3, 224)), the message at least one of, (a) prompting a user to initiate performance of another predetermined laboratory test, (b) informing a user of potential reasons for the failure condition, (c) prompting a user to repeat the laboratory test, (d) prompting a user with a user predetermined message and (e) identifying an expected result and actual result of the laboratory test (page 15, lines 21-24; Figure 7a, 708, 710).

Dependent claim 12 includes the features of independent claim 1 and claim 3 along with the additional feature of one of the plurality of validation preconditions corresponds

to an elapsed time period to wait before comparing the laboratory test result with the expected test result, the elapsed time period being a time period following initiation of the laboratory test (page 6, lines 7-11; Figure 2, 230).

Dependent claim 13 includes the features of independent claim 1 along with the additional feature that the result processor initiates generation of an alert message to a user prompting a user to enter an override command indicating whether the failure condition is to be overridden (page 14, lines 13-16; Figure 7a, 716).

Dependent claim 14 includes the features of independent claim 1 and claim 13 along with the additional feature that the result processor initiates storage of a record indicating the failure condition was overridden, in response to the user override command (page 13, lines 14-16; Figure 6, 420. 422). The record at least one of, (a) is accessible by an authorized person (page 13, lines 18-20; Figure 6, 420), (b) provides an audit trail indicating a person entering the override command and (c) is incorporated in a report identifying override command occurrences (page 17, lines 18-23; Figure 10, 1000).

Dependent claim 15 includes the features of independent claim 1 and claim 13 along with the additional feature that an authorization processor determines whether a user is authorized to override the failure condition and inhibits the override in response to a determination the user is unauthorized (page 14, lines 24-28; Figure 7a, 716).

Dependent claim 16 includes the features of independent claim 1 along with the additional feature that the result processor initiates generation of an alert message with a plurality of different warning severity message levels (page 14, lines 29-31; Figure 7a, 702).

Independent claim 17 describes a user interface system for use processing information related to laboratory tests and results. A display processor initiates generation of at least one display image including display elements. A user is enabled to enter data identifying a laboratory test result of a patient specimen culture (page 2, lines 31-32; Figure 1, 2) and to enter data identifying an expected result of the laboratory test and one or more validation pre-conditions (page 5, lines 33 to page 6, line 2). An alert message is displayed to a user indicating a failure condition derived by employing one or more user determined validation pre-conditions in comparing the laboratory test result with the expected test result and by determining a failure condition in response to the laboratory test result failing to match the expected test result (page 2, line 33 to page 3, line 2; Figure 1, 4, 6).

Dependent claim 18 includes the features of independent claim 17 along with the additional feature that at least one display image includes display elements for enabling a user to enter data identifying an expected result of the laboratory test comprising at least one of, (a) an identifier indicating a culture is resistant to a test compound, (b) an identifier indicating a culture is sensitive to a test compound, (c) an identifier indicating a positive test result and (d) an identifier indicating a negative test result and (e) a quantity identifier indicating presence of an approximate quantity of microbes per unit area of a culture (page 11, lines 6-9; Figure 5d, 606).

Dependent claim 19 includes the features of independent claim 17 along with the additional feature that the at least one display image includes display elements for displaying an alert message to a user prompting a user enter an override command

indicating whether the failure condition is to be overridden (page 14, lines 12-16; Figure 7a, 716).

Independent claim 20 describes a system for processing information related to laboratory tests and results. An interface processor receives user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test (page 5, line 33 to page 6, line 2; page 6, line 7; Figure 2, 236). A validation processor employs one or more user determined validation pre-conditions in comparing an individual result of the plurality of expected test results with a corresponding individual laboratory test result of the plurality of test results and identifies a failure condition in response to the individual laboratory test result failing to match the corresponding expected test result (page 10, line 4 to page 11, line 2; Figure 1, 4). A result processor initiates generation of an alert message to a user indicating a failure conditions of the individual test performed at a particular time stage of the different time stages (page 11, lines 4-5; Figure 7a, 700).

Independent claim 21 describes a method for processing information related to laboratory tests and results. User entered data identifying a laboratory test result of a patient specimen culture is received (page 2, lines 31-32; Figure 1, 2). One or more user determined validation pre-conditions is employed in comparing the laboratory test result with the expected test result (page 10, lines 4-5; Figure 1, 4). A failure condition is identified in response to the laboratory test result failing to match the expected test result (page 10, line 10 to page 11, line 2). Generation of an alert message to a user indicating the failure condition is initiated (page 11, lines 4-5; Figure 7a, 700).

Independent claim 22 describes a method for processing information related to laboratory tests and results. User entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test is received (page 5, line 22 to page 6, line 2; page 6, line 7; Figure 2, 236). One or more user determined validation pre-conditions is employed in comparing an individual result of the plurality of expected test results with a corresponding individual laboratory test result of the plurality of test results (page 10, lines 4 to 6; Figure 1, 4). A failure condition is identified in response to the individual laboratory test result failing to match the corresponding expected test result (page 10, line 10 to page 11, line 2). Generation of an alert message to a user indicating a failure condition of the individual test performed at a particular time stage of the different time stages is initiated (page 11, lines 4-5; Figure 7a, 700).

Independent claim 23 describes a user interface system for processing information related to laboratory tests and results. A display processor initiates generation of at least one display image including display elements. A user is enabled to enter data identifying an expected laboratory test result, a laboratory test result; at least one further expected laboratory test result, at least one further laboratory test result; and a plurality of validation pre-conditions for validating the first laboratory test, and for displaying an alert message to a user indicating a failure condition (page 5, lines 20-24; Figure 2, 236). One or more user determined validation pre-conditions are employed in comparing the expected laboratory test result with the laboratory test result and identifying a first failure condition in response to the laboratory test result failing to match the expected laboratory test result (page 10, line 10 to page 11, line 2; Figure 1, 4). The at least one further laboratory test result is compared with the at least one further expected laboratory test result and a second failure condition is identified in response to the at least one further laboratory test result

failing to match the at least one further expected laboratory test result. It is determined that at least one of the plurality of validation pre-conditions is not satisfied (page 11, lines 2-4; Figure 7a, 700).

Independent claim 24 describes a method for processing information related to laboratory tests and results. User entered data is received comprising an expected first laboratory test result of a first laboratory test requiring validation processing; an actual first laboratory test result; at least one further expected laboratory test result of at least one further laboratory test for validating the first laboratory test; at least one further actual laboratory test result of the at least one further laboratory test; and a plurality of validation pre-conditions (page 5, lines 19-24; Figure 2, 200). One or more user determined validation pre-conditions are employed in comparing the expected first laboratory test result with the actual first laboratory test result (page 10, lines 4-5; Figure 1, 4). A first failure condition is identified in response to the expected first laboratory test result failing to match the actual first laboratory test result (page 10, line 10 to page 11, line 2). The at least one further expected laboratory test result is compared with the at least one further actual laboratory test result (page 11, lines 2-4). A second failure condition is identified in response to the at least one further expected laboratory test result failing to match the at least one further actual laboratory test result (page 11, lines 2-4; Figure 7a, 700). A third failure condition is identified when the plurality of validation pre-conditions are not satisfied (page 2, line 34 to page 3, line 1; Figure 7a, 700).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-5, 7, 9-11, 13, 14 and 17-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Schaeffer et al. (U.S. PG Pub No. US 2002/0107641).

Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaeffer et al. (U.S. PG Pub No. US 2002/0107641) as applied to claim 1 above, and further in view of Peck et al. (U.S. Patent 5,789,173).

Claims 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaeffer et al. (U.S. PG Pub No. US 2002/0107641) as applied to claim 1 above, and further in view of Buechler et al. (U.S. Patent 6,830,731).

VII. ARGUMENT

The rejections that are formal in nature will be addressed following a decision on this appeal brief.

Schaeffer when taken alone or in any combination with Peck and/or Buechler neither anticipate nor make the present claimed invention unpatentable. Thus, reversal of the Final Rejection (hereinafter termed "rejection") of claims 1-25 under 35 U.S.C. § 102(e) and 103(a) is respectfully requested.

Overview of the Cited References

Schaeffer recites a method for the construction and utilization of a medical records system capable of providing a continuous data stream of epidemiological data to the records system. Kits are provided to the symptomatic population to obtain and record an epidemiological profile in a searchable database. When a valid epidemiological profile is established in the database, automated diagnosis and prescription of treatment may be had for patients presenting similar symptoms. Knowledge discovery techniques may further operate on the database to provide suggested courses of treatment for a virtual class of

patients, epidemic threat awareness, and knowledge of drug resistance mutations by a pathogen without direct query of the database (see Abstract).

Peck recites a method for rapid antimicrobial susceptibility testing to screen antibiotics in a few hours instead of days by conventional methods. This method can also be used to identify susceptible antibiotics to treat mycobacterial infection in a few days instead of the usual six to eight weeks. Fast screening of antibiotics is achieved by a short period of specimen incubation in different antibiotics embedded media to create differential bacterial counts. The differences of bacterial counts among antibiotics embedded media are subsequently amplified by DNA amplification methods for detection. Following DNA amplification, rapid quantization and minimum inhibition concentration (MIC) determinations for a panel of antibiotics are achieved in less than one minute by fluorescence quantization methods (see Abstract).

Buechler recites a fluorometer for sensing the fluorescence of a sample utilizes an optical energy source for exciting a sample to be tested and an optical energy detector for detecting the emitted energy from the excited sample. Drive electronics are used for positioning the sample with respect to the optical components allowing a plurality of sample regions to be tested. A processor is utilized to control the operation of the test in accordance with test instructions and for processing the emitted energy detected from the sample to determine test results. A communications interface facilitates the sharing of test information between the fluorometer and external entities (see Abstract).

Rejection of Claims 1-5, 7, 9-11, 13, 14 and 17-25 under U.S.C. 102(e) over Schaeffer (U.S. PG Pub No. US 2002/0107641)

Reversal of the rejection of claims 1-5, 7, 9-11, 13, 14 and 17-25 under 35 U.S.C. 102(e) as being anticipated by U.S. PG Pub No. US 2002/0107641 issued to Schaeffer is respectfully requested because the rejection makes crucial errors in interpreting the cited reference. The rejection erroneously states that claims 1-5, 7, 9-11, 13, 14 and 17-25 are anticipated by Schaeffer.

CLAIM 1

Claim 1 recites a system for "processing information related to laboratory tests and results" comprising "an interface processor for receiving user entered data identifying a laboratory test result of a patient specimen culture and for receiving user entered data identifying an expected result of said laboratory test and data identifying a validation pre-condition; a validation processor for employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result; and a result processor for initiating generation of an alert message to a user indicating said first failure condition." These features are not shown (or suggested) in Schaeffer.

The laboratory test result processing system of claim 1 receives "user entered data identifying a laboratory test result of a patient specimen culture" and "user entered data identifying an expected result of said laboratory test and data identifying a validation pre-condition." A "validation processor" employs "one or more user determined validation pre-conditions in comparing the laboratory test result with the expected test result" and identifies a "first failure condition in response to said laboratory test result failing to match said expected test result." These features are neither shown nor suggested in Schaeffer or the other references. The claimed system "addresses the need for an improved

microbiology validation system. During a culture's 'testing lifecycle' in a clinical microbiology laboratory, numerous results are entered and released over a course of hours, days or weeks." The system "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2, lines 24-29). The system advantageously performs "validations of test cultures by continuously monitoring and comparing test results as they occur with previously obtained test results throughout the lifecycle of a culture. A further advantage provided by the invention is a capability to monitor test results that are entered throughout the lifecycle of a culture. The invention also advantageously considers specific quantities when defining expected results and alerts a user of unexpected results prior to their release to a physician for review. A still further advantage allows a user to define who can override a validation failure" (Application page 3, line 29 to page 4, line 4). The claimed features as well as associated problems addressed and advantages are not recognized or contemplated in Schaeffer.

Schaeffer does NOT show or suggest "receiving user entered data identifying a laboratory test result of a patient specimen culture" and "receiving user entered data identifying an expected result of said laboratory test and data identifying a validation pre-condition" and "a validation processor for employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result." Schaeffer "teaches the use of data mining approaches to better predict the pathogen encountered and to provide better medical practitioner guidance with respect to the undiagnosed patient. This is particularly crucial within this application since susceptibilities and tolerance to pathogen mutations and their

treatment rapidly change" (Schaeffer par. 0035). Schaeffer is concerned with the management of predicted diseases in patients with specific symptoms. The predictions are based on the historical epidemiological data such as epidemiology profiles, patient demographics and similar symptoms and are used to suggest courses of treatment. Schaeffer describes how the historical data is entered into the system (para. 0049, 0050), and how the data can be cleaned i.e. to remove patient specific identification information (para. 0072) and how the data can be retrieved and sorted (para. 0087).

Schaeffer, contrary to the Rejection statements on page 3 does not show or suggest in para. 0044 or elsewhere "receiving user entered data identifying a laboratory test result of a patient specimen culture" and "receiving user entered data identifying an expected result of said laboratory test and data identifying a validation pre-condition." Schaeffer in para. 0044 merely indicates "The present invention thus allows prediction, or diagnosis, for the particular patient" which "may preferably be done for the patient **prior to**, or in the **absence of**, obtaining a sample, and analyzing the sample, from the particular patient." Schaeffer in paragraph 0044 advocates prediction of diagnosis without "receiving user entered data identifying a laboratory test result" and certainly provides no suggestion at all of "receiving **user entered** data identifying an expected result of said laboratory test and data identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in **comparing** said laboratory test result with said **expected** test result and identifying a **first failure condition** in response to said laboratory test result failing to match said expected test result."

Applicant further respectfully disagrees with the assertion on page 9 of the Rejection that page 4 [0048] and pages 7-8 [0081] of Schaeffer describe "receiving user entered data identifying an expected result of said laboratory test and data identifying a

validation pre-condition" as recited in the present claimed invention. Rather, page 4 [0048] describes the types and source of information that is taken into consideration when predicting the possible infection/disease of a patient. This information emphasizes patient demographics, but can also include results from cultures (such as Urine, throat etc.). The culture results that are being described are results that have **already been released** from the laboratory performing the tests. These results, plus the other information, are used by Schaeffer to predict a disease. The present invention, on the other hand, describes a validation processor that is utilized within the laboratory to facilitate the workflow of a technologist while performing a culture "work-up" **prior to the release** of the results to the physician. It is not used to predict disease. It is a rules based processor that will guide and alert the user based on predefined parameters. Pages 7-8 [0081] of Schaeffer describe using probabilities, based on previously entered data, to determine conditions. The present invention, on the other hand, can be tailored by the user and utilized to the extent they desire. The processor can be programmed to utilize known patterns; it can even be utilized to "remind" the user of additional workflow steps (page 13, lines 10-14).

Schaeffer teaches data mining of historical epidemiological data may be used to predict a pathogen and does NOT suggest user entry of "data identifying an expected result" of a "laboratory test." On the contrary, the Schaeffer method is intended to be performed prior to, or in the absence of, a culture (Para. 0044) and consequently is wholly **independent** of a "laboratory test." In addition, Schaeffer in paragraphs 0052, 0056 or elsewhere does not suggest a user interface for "receiving" "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result." There is no mention in para. 0056 and 0074 or elsewhere in

Schaeffer of a "pre-condition" at all and no suggestion of a user interface for "receiving" "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in **comparing** said laboratory test result **with** said **expected** test result and identifying a **first failure condition** in response to said laboratory test result failing to match said expected test result."

Applicant further respectfully disagrees with the assertion on page 10 of the Rejection stating that Schaeffer on page 7 [0071], lines 13-15 describes the present invention. This passage describes how the data is retrieved from the database. Naturally, this data must be entered somehow. Schaeffer requires the user to actively "request" or query the database to retrieve an answer. The present claimed invention, on the other hand, does not require the user to actively "request" an answer based on the rule parameters that are defined. The inventive system processor is "always on" and continuously monitors the workflow of the user. When the user initiates certain functions (ex. "result release"), the rules are triggered and if necessary, a message is displayed for the user. The inventive system employs workflow tool, not a database used only when a specific query is initiated as with Schaeffer.

Schaeffer in para. 0056 mentions a determination "if the identity of the antimicrobial is provided" of a "person's outcome at the completion of the course of treatment" and "whether the antimicrobial is effective for treating the identified bacterium. That is, whether the symptoms are resolved by completion of the course of antimicrobial treatment is an indicator as to whether the antimicrobial taken is effective in treating the bacterial infection." However, whether or not a course of antimicrobial treatment is effective in **treating** a patient has nothing to do with whether or not a "laboratory test result" meets user entered "pre-condition" criteria. A treatment outcome is NOT (and does

not suggest) a "laboratory test result." Consequently, Schaeffer fails to suggest a user interface for "receiving" "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in **comparing** said laboratory test result **with** said **expected** test result and identifying a **first failure condition** in response to said laboratory test result failing to match said expected test result." Paragraph 0074 of Schaeffer relied on in the Rejection on page 3 concerns "data cleaning" and has no bearing on "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result."

Applicant respectfully submits that contrary to page 10 of the rejection, Schaeffer on page 8, [0086] does not describe "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result" as recited in the present claimed invention. This passage of Schaeffer describes the evaluation of patterns which are used to determine the confidence level of the data. Confidence levels are required by this invention because predictions are being made based on historical data being queried. The confidence levels assist the physician in determining if the prediction should be followed, as in the case of predicting the outcome of a particular treatment on a virtual patient (Schaeffer, [091] lines 16-23). The present claimed invention, however, is based on known patterns (accepted patterns that are known within the art) or known hospital procedures. The rule parameter values are defined based on these patterns or procedures. When a result or results are entered and trigger a message to display, the user knows that the pattern does not match. There is no need for confidence levels. The inventive system allows for three severity levels, which further assist the user in determining their next step.

Schaeffer in para. 0087 relied on in the Rejection on page 3 also fails to show or suggest a "result processor for initiating generation of an alert message to a user indicating" a "first failure condition." Paragraph 0087 merely discusses generation of reports from a database and provides no 35 USC 112 compliant enabling disclosure of "initiating generation of an alert message to a user indicating" a "first failure condition" derived by employing "validation pre-conditions in **comparing** said laboratory test result **with** said **expected** test result." Schaeffer is not concerned with facilitating the operation of laboratory testing or of providing a system that "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2, lines 24-29). On the contrary, Schaeffer discloses a function that is performed **prior to**, or in the **absence** of, a culture (Para. 0044) and consequently is wholly **independent** of a "laboratory test".

The Schaeffer system "relates to the management of diagnosis and treatment of infections prior to or in the absence of culturing the pathogen prior to commencing treatment" (para. 0002). In contrast, the claimed system "addresses the need for an improved microbiology validation system. **During a culture's 'testing lifecycle'** in a clinical micro-biology laboratory" (Application page 2, lines 24-29). Schaeffer teaches the use of data mining for prediction of pathogens, diagnosis or treatment **prior to** or in **the absence of culturing** the pathogen whereas the claimed system supports the identification of causative pathogens that have been recovered and isolated from patient cultures. The Schaeffer and claimed systems are fundamentally different, address different problems, and Schaeffer fails to show or suggest the claimed arrangement. Consequently, withdrawal of the Rejection of claim 1 under 35 U.S.C. 102(e) based on Schaeffer is respectfully requested.

CLAIM 2

Dependent claim 2 is considered to be patentable based on its dependence on claim 1. Therefore, the arguments presented above with respect to claim 1 also apply to claim 2. Claim 2 is also considered to be patentable because Schaeffer neither discloses nor suggests a system including an "interface processor" that "further receives user entered data identifying at least one further laboratory test result of said patient and user entered data identifying at least one further expected laboratory test result of said at least one further laboratory test; and wherein said validation processor compares said at least one further laboratory test result with said at least one further expected laboratory test result and identifies a second failure condition in response to said at least one further laboratory test result of said patient failing to match said at least one further expected laboratory test result; and wherein said result processor initiates generation of an alert message to a user indicating said second failure condition" as recited in the present claimed invention. As previously explained in connection with claim 1, Schaeffer discloses a function that is performed **prior to**, or in the **absence** of, a culture and consequently is wholly **independent** of a "laboratory test" (Schaeffer para. 0044).

Schaeffer provides no 35 USC 112 compliant enabling disclosure of "initiating generation of an alert message to a user indicating" a "**second** failure condition" derived when "said validation processor compares said at least one **further laboratory test result** with said at least one **further expected** laboratory test result and identifies a second failure condition in response to said at least one further laboratory test result of said patient". Schaeffer nowhere suggests any comparison of an individual **laboratory test** result with an expected laboratory test result and certainly not a **multiple** test comparison involving a "validation processor" that "compares said at least one further laboratory test result with

said at least one further expected laboratory test result and identifies a second failure condition in response to said at least one further laboratory test result". Consequently, it is respectfully requested that the rejection of claim 2 under 35 USC 102(e) be withdrawn.

CLAIM 3

Dependent claim 3 is considered to be patentable based on its dependence on claim 1. Therefore, the arguments presented above with respect to claim 1 also apply to claim 3. Claim 3 is also considered to be patentable because Schaeffer neither discloses nor suggests a system in which an "interface processor further receives user entered data identifying a plurality of validation pre-conditions for validating said laboratory test of said patient; wherein said validation processor identifies a second failure condition when at least one of said plurality of validation pre-conditions are not satisfied; and wherein said result processor initiates generation of an alert message to a user indicating said second failure condition" as recited in the present claimed invention. As previously explained in connection with claim 1, Schaeffer discloses a function that is performed **prior to**, or in the **absence** of, a culture (Para. 0044) and consequently is wholly **independent** of a "laboratory test."

Schaeffer provides no 35 USC 112 compliant enabling disclosure of an "interface processor" that "further receives user entered data identifying a plurality of validation pre-conditions for validating said laboratory test of said patient; wherein said validation processor identifies a second failure condition when at least one of said plurality of validation pre-conditions are not satisfied. Schaeffer also fails to suggest initiating "generation of an alert message to a user indicating" a "second failure condition" derived "when at least one of said plurality of validation pre-conditions are not satisfied". Schaeffer nowhere suggests any comparison of an individual laboratory test result with an

expected laboratory test result and not a test comparison involving a "plurality of validation pre-conditions" that "identifies a **second failure condition** when at least one of said plurality of validation pre-conditions are not satisfied". Whether or not a course of antimicrobial treatment is effective in **treating** a patient (para. 0056 relied upon in the Rejection on page 4) has nothing to do with whether or not a "**laboratory test** result" meets user entered "pre-condition" criteria. Consequently, it is respectfully requested that the rejection of claim 3 under 35 USC 102(e) be withdrawn.

CLAIM 4

Dependent claim 4 is considered to be patentable based on its dependence on claim 1. Therefore, the arguments presented above with respect to claim 1 also apply to claim 4. Claim 4 is also considered to be patentable because Schaeffer neither discloses nor suggests a system in which "said received user entered data identifying an expected result of said laboratory test comprises at least one of, (a) an identifier indicating a culture is **resistant** to a test compound, (b) an identifier indicating a culture is **sensitive** to a test compound, (c) an identifier indicating a **positive** test result and (d) an identifier indicating a **negative** test result" as recited in the present claimed invention. As previously explained in connection with claim 1, Schaeffer in para. 0044 discloses a function that is performed prior to, or in the absence of, a culture and consequently is wholly independent of a "laboratory test" and fails to show or suggest in para. 0056 or elsewhere employing "user entered data identifying an expected result of said laboratory test" as recited in the present claimed invention. Consequently, it is respectfully requested that the rejection of claim 4 under 35 USC 102(e) be withdrawn.

CLAIM 5

Dependent claim 5 is considered to be patentable based on its dependence on claim 1. Therefore, the arguments presented above with respect to claim 1 also apply to claim 5. Claim 5 is also considered to be patentable because Schaeffer neither discloses nor suggests a system in which "said received user entered data identifying an expected result of said laboratory test comprises a quantity identifier indicating presence of an approximate quantity of microbes per unit area of a culture" as recited in the present claimed invention. As previously explained in connection with claim 1, Schaeffer discloses in para. 0044 a function that is performed prior to, or in the absence of, a culture and consequently is wholly independent of a "laboratory test". Schaeffer fails to show or suggest in para. 0053 or elsewhere employing "user entered data identifying an expected result of said laboratory test comprises a quantity identifier indicating presence of an approximate quantity of microbes per unit area of a culture" as recited in the present claimed invention. The "detectable amounts of bacteria" in para. 0053 relied upon in the Rejection on page 4 have no bearing on employing "user entered data identifying an expected result of said laboratory test" that comprises "a **quantity identifier** indicating presence of an approximate **quantity of microbes per unit area** of a culture." No such "quantity identifier" is suggested in Schaeffer. Consequently, it is respectfully requested that the rejection of claim 5 under 35 USC 102(e) be withdrawn.

CLAIM 9

Dependent claim 9 is considered to be patentable based on its dependence on claim 1. Therefore, the arguments presented above with respect to claim 1 also apply to claim 9. Claim 9 is also considered to be patentable because Schaeffer neither discloses nor suggests a system in which "said received user entered data identifies a plurality of expected results of said laboratory test and said validation processor compares a plurality of laboratory test results with said plurality of expected results and identifies a failure

condition in response to a predetermined condition if at least one of said plurality of laboratory test results fails to match a corresponding one of said plurality of expected results" as recited in the present claimed invention. As previously explained in connection with claim 1, Schaeffer discloses in para. 0044 a function that is performed prior to, or in the absence of, a culture and consequently is wholly independent of a "laboratory test". Additionally, para. 0059 of Schaeffer merely describes organizing the information in the searchable medical record system. Schaeffer fails to show or suggest in para. 0044, 0059 or elsewhere, employing "received user entered data" that "identifies a plurality of expected results of said laboratory test" and comparing "a plurality of laboratory test results with said plurality of expected results" and identifying "a failure condition in response to a predetermined condition if at least one of said plurality of laboratory test results fails to match a corresponding one of said plurality of expected results" as recited in the present claimed invention. Consequently, it is respectfully requested that the rejection of claim 9 under 35 USC 102(e) be withdrawn.

CLAIM 10

Dependent claim 10 is considered to be patentable based on its dependence on claim 1. Therefore, the arguments presented above with respect to claim 1 also apply to claim 10. Claim 10 is also considered to be patentable because Schaeffer neither discloses nor suggests a system in which "said interface processor receives user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at **different time stages** of a laboratory test, said validation processor compares an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results and identifies a failure condition in response to said individual laboratory test result failing to match said corresponding expected test result; and said result processor initiates generation of an alert message to a

user indicating a failure condition of said individual test performed at a particular time stage of said different time stages" as recited in the present claimed invention. Schaeffer in para. 0044 merely indicates "The present invention thus allows prediction, or diagnosis, for the particular patient" which "may preferably be done for the patient **prior to**, or in the **absence of**, obtaining a sample, and analyzing the sample, from the particular patient." Paragraph 0044 of Schaeffer advocates prediction of diagnosis **without** receiving "user entered data identifying a laboratory test result" and certainly provides no suggestion at all of "receives user entered data identifying a plurality of results **expected** for a corresponding plurality of test results derived at **different time stages** of a laboratory test" and comparing "an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results" as recited in the present claimed invention.

Further, Schaeffer in para. 0087 relied on in the Rejection on page 5 also fails to show or suggest "initiating generation of an alert message to a user indicating" a "failure condition" as recited in the present claimed invention. Paragraph 0087 merely discusses generation of reports from a database and provides no 35 USC 112 compliant enabling disclosure of such a feature. Schaeffer is not concerned with facilitating the operation of laboratory testing or of providing a system that "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2 lines 24-29). On the contrary Schaeffer discloses a function that is performed **prior to**, or in the **absence** of, a culture (Para. 0044) and consequently is wholly **independent** of a "laboratory test". Thus, applicant respectfully requests that the rejection of claim 10 under 35 U.S.C. 102(e) be withdrawn.

CLAIM 11

Dependent claim 11 is considered to be patentable based on its dependence on claim 1. Therefore, the arguments presented above with respect to claim 1 also apply to claim 11. Claim 11 is also considered to be patentable because Schaeffer neither discloses nor suggests a system in which "said result processor initiates generation of an alert message to a user in response to occurrence of said failure condition, said message at least one of, (a) prompting a user to initiate performance of another predetermined laboratory test, (b) informing a user of potential reasons for said failure condition, (c) prompting a user to repeat said laboratory test, (d) prompting a user with a user predetermined message and (e) identifying an expected result and actual result of said laboratory test" as recited in the present claimed invention. Schaeffer in para. 0087 relied on in the Rejection on page 5 fails to show or suggest "initiating generation of an alert message to a user indicating" a "failure condition". Paragraph 0087 merely discusses generation of reports from a database and provides no 35 USC 112 compliant enabling disclosure of "initiating generation of an alert message to a user indicating" a "failure condition". Schaeffer is not concerned with facilitating the operation of laboratory testing or of providing a system that "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2 lines 24-29). On the contrary, para. 0044 of Schaeffer discloses a function that is performed **prior to**, or in the **absence** of, a culture and consequently is wholly **independent** of a "laboratory test" of said plurality of test results". Consequently, it is respectfully requested that the rejection of claim 11 under 35 USC 102(e) be withdrawn.

CLAIM 13

Dependent claim 13 is considered to be patentable based on its dependence on claim 1. Therefore, the arguments presented above with respect to claim 1 also apply to claim 13. Claim 13 is also considered to be patentable because Schaeffer neither discloses nor suggests a system in which "said result processor initiates generation of an alert message to a user prompting a user to enter an override command indicating whether said failure condition is to be overridden" as recited in the present claimed invention. Schaeffer in para. 0090 relied on in the Rejection on page 5 fails to show or suggest initiating "generation of an alert message to a user prompting a user to enter an override command indicating whether said failure condition is to be overridden". Paragraph 0090 merely discusses generation of reports from a database and provides no 35 USC 112 compliant enabling disclosure of such a feature and there is no mention or suggestion of overriding a command at all. Consequently, it is respectfully requested that the rejection of claim 13 under 35 USC 102(e) be withdrawn.

CLAIM 14

Dependent claim 14 is considered to be patentable based on its dependence on claim 1. Therefore, the arguments presented above with respect to claim 1 also apply to claim 14. Claim 14 is also considered to be patentable because Schaeffer neither discloses nor suggests a system in which "said result processor initiates storage of a record indicating said failure condition was overridden, in response to said user override command, said record at least one of, (a) being accessible by an authorized person, (b) providing an audit trail indicating a person entering said override command and (c) being incorporated in a report identifying override command occurrences" as recited in the present claimed invention. Schaeffer in para. 0090 relied on in the Rejection on page 5 merely discusses generation of reports from a database and provides no 35 USC 112 compliant enabling disclosure of such a feature and there is no mention or suggestion of overriding a command

at all. Consequently, it is respectfully requested that the rejection of claim 13 under 35 USC 102(e) be withdrawn.

CLAIMS 17 and 18

Claim 17 recites a system for "processing information related to laboratory tests and results" comprising "a display processor for initiating generation of at least one display image including display elements for enabling a user to enter data identifying a laboratory test result of a patient specimen culture and to enter data identifying an expected result of said laboratory test and one or more validation pre-conditions, and for displaying an alert message to a user indicating a failure condition derived by employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and by determining a failure condition in response to said laboratory test result failing to match said expected test result." These features are neither shown nor suggested in Schaeffer.

The laboratory test result processing system of claim 17 enables a "user to enter data identifying a laboratory test result of a patient specimen culture and to enter data identifying an expected result of said laboratory test and one or more validation pre-conditions." The system employs "one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result" and indicates a "failure condition in response to said laboratory test result failing to match said expected test result." These features are neither shown nor suggested in Schaeffer or the other references. The claimed system "addresses the need for an improved microbiology validation system. During a culture's 'testing lifecycle' in a clinical micro-biology laboratory, numerous results are entered and released over a course of hours, days or weeks." The system "improves upon this process by providing techniques that consider the

results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2, lines 24-29). As described with respect to claim 1, the system advantageously performs "validations of test cultures by continuously monitoring and comparing test results as they occur with previously obtained test results throughout the lifecycle of a culture. A further advantage provided by the invention is a capability to monitor test results that are entered throughout the lifecycle of a culture. The invention also advantageously considers specific quantities when defining expected results and alerts a user of unexpected results prior to their release to a physician for review. A still further advantage allows a user to define who can override a validation failure" (Application page 3, line 29 to page 4, line 4). The claimed features as well as associated problems addressed and advantages are not recognized or contemplated in Schaeffer.

Schaeffer does NOT show or suggest "enabling a user to enter data identifying a laboratory test result of a patient specimen culture" and "to enter data identifying an expected result of said laboratory test and one or more validation pre-conditions" and "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and by determining a failure condition in response to said laboratory test result failing to match said expected test result." Schaeffer "teaches the use of data mining approaches to better predict the pathogen encountered and to provide better medical practitioner guidance with respect to the undiagnosed patient. This is particularly crucial within this application since susceptibilities and tolerance to pathogen mutations and their treatment rapidly change" (Schaeffer par. 0035). Schaeffer is concerned with the management of predicted diseases in patients with specific symptoms. The predictions are based on the historical epidemiological data such as epidemiology profiles, patient demographics and similar symptoms and are used to suggest courses of

treatment. Schaeffer describes how the historical data is entered into the system (para. 0049, 0050), and how the data can be cleaned i.e. to remove patient specific identification information (para. 0072) and how the data can be retrieved and sorted (para. 0087).

Schaeffer does not show or suggest in para. 0044 or elsewhere "enabling a user to enter data identifying a laboratory test result of a patient specimen culture" and "to enter data identifying an expected result of said laboratory test and one or more validation pre-conditions." Schaeffer in para. 0044 merely indicates "The present invention thus allows prediction, or diagnosis, for the particular patient" which "may preferably be done for the patient **prior to**, or in the **absence of**, obtaining a sample, and analyzing the sample, from the particular patient." Schaeffer in paragraph 0044 advocates prediction of diagnosis without "enabling a user to enter data identifying a laboratory test result" and certainly provides no suggestion at all of a **user entering** "data identifying a laboratory test result of a patient specimen culture...and data identifying an expected result of said laboratory test and one or more validation pre-conditions" and "employing one or more user determined validation pre-conditions in **comparing** said laboratory test result with said **expected** test result and by determining a **failure condition** in response to said laboratory test result failing to match said expected test result."

Applicant further respectfully disagrees with the assertion on page 9 of the Rejection that page 4 [0048] and pages 7-8 [0081] of Schaeffer describe "enabling a user to enter data identifying a laboratory test result of a patient specimen culture and to enter data identifying an expected result of said laboratory test and one or more validation pre-conditions" as recited in the present claimed invention. Rather, page 4 [0048] describes the types and source of information that is taken into consideration when predicting the possible infection/disease of a patient. This information emphasizes patient demographics,

but can also include results from cultures (such as Urine, throat etc.). The culture results that are being described are results that have **already been released** from the laboratory performing the tests. These results, plus the other information, are used by Schaeffer to predict a disease. The present invention, on the other hand, describes a system that is utilized within the laboratory to facilitate the workflow of a technologist while performing a culture "work-up" **prior to the release** of the results to the physician. It is not used to predict disease. It is a rules based system that will guide and alert the user based on predefined parameters. Pages 7-8 [0081] of Schaeffer describe using probabilities, based on previously entered data, to determine conditions. The present invention, on the other hand, can be tailored by the user and utilized to the extent they desire. The processor can be programmed to utilize known patterns; it can even be utilized to "remind" the user of additional workflow steps (page 13, lines 10-14).

Schaeffer teaches data mining of historical epidemiological data may be used to predict a pathogen and does NOT suggest user entry of "data identifying an expected result" of a "laboratory test." On the contrary, the Schaeffer method is intended to be performed prior to, or in the absence of, a culture (Para. 0044) and consequently is wholly **independent** of a "laboratory test." In addition, Schaeffer in paragraphs 0052, 0056 or elsewhere does not suggest a enabling a user to "enter data identifying an expected result of said laboratory test and one or more validation pre-conditions" and "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and by determining a failure condition in response to said laboratory test result failing to match said expected test result." There is no mention in para. 0056 and 0074 or elsewhere in Schaeffer of a "pre-condition" at all and no suggestion of a user interface for enabling a user to "enter data identifying an expected result of said laboratory test and one or more validation pre-conditions" and "employing one or more

user determined validation pre-conditions in **comparing** said laboratory test result **with** said **expected** test result and by determining a **failure condition** in response to said laboratory test result failing to match said expected test result."

Applicant further respectfully disagrees with the assertion on page 10 of the Rejection stating that Schaeffer on page 7 [0071], lines 13-15 describes the present invention. This passage describes how the data is retrieved from the database. Naturally, this data must be entered somehow. Schaeffer requires the user to actively "request" or query the database to retrieve an answer. The present claimed invention, on the other hand, does not require the user to actively "request" an answer based on the rule parameters that are defined. The inventive system processor is "always on" and continuously monitors the workflow of the user. When the user initiates certain functions (ex. "result release"), the rules are triggered and if necessary, a message is displayed for the user. The inventive system comprises a workflow tool, not a database used only when a specific query is initiated as with Schaeffer.

Schaeffer in para. 0056 mentions a determination "if the identity of the antimicrobial is provided" of a "person's outcome at the completion of the course of treatment" and "whether the antimicrobial is effective for treating the identified bacterium. That is, whether the symptoms are resolved by completion of the course of antimicrobial treatment is an indicator as to whether the antimicrobial taken is effective in treating the bacterial infection." However, whether or not a course of antimicrobial treatment is effective in **treating** a patient has nothing to do with whether or not a "laboratory test result" meets user entered "pre-condition" criteria. A treatment outcome is NOT (and does not suggest) a "laboratory test result." Consequently, Schaeffer fails to suggest "enabling a user to" "enter data identifying an expected result of said laboratory test and one or more

validation pre-conditions" and "employing one or more user determined validation pre-conditions in **comparing** said laboratory test result **with** said **expected** test result and by determining a **failure condition** in response to said laboratory test result failing to match said expected test result." Paragraph 0074 of Schaeffer relied on in the Rejection on page 3 concerns "data cleaning" and has no bearing on "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result."

Applicant respectfully submits that contrary to page 10 of the rejection, Schaeffer on page 8, [0086] does not describe "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and by determining a failure condition in response to said laboratory test result failing to match said expected test result" as recited in the present claimed invention. This passage of Schaeffer describes the evaluation of patterns which are used to determine the confidence level of the data. This is required by this invention because predictions are being made based on historical data being queried. The confidence levels assist the physician in determining if the prediction should be followed, as in the case of predicting the outcome of a particular treatment on a virtual patient (Schaeffer, [091] lines 16-23). The present claimed invention, however, is based on known patterns (accepted patters that are known within the art) or known hospital procedures. The rule parameter values are defined based on these patterns or procedures. When a result or results are entered and trigger a message to display, the user knows that the pattern does not match. There is no need for confidence levels. The inventive system allows for three severity levels, which further assist the user in determining their next step.

Schaeffer in para. 0087 relied on in the Rejection on page 3 also fails to show or suggest an "alert message to a user indicating a failure condition." Paragraph 0087 merely discussed generation of reports from a database and provides no 35 USC 112 compliant enabling disclosure of "displaying an alert message to a user indicating a failure condition" derived by employing "one or more user determined validation pre-conditions in **comparing** said laboratory test result **with** said **expected** test result." Schaeffer is not concerned with facilitating the operation of laboratory testing or of providing a system that "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2, lines 24-29). On the contrary Schaeffer discloses a function that is performed **prior to**, or in the **absence** of, a culture (Para. 0044) and consequently is wholly **independent** of a "laboratory test".

The Schaeffer system "relates to the management of diagnosis and treatment of infections prior to or in the absence of culturing the pathogen prior to commencing treatment" (para. 0002). In contrast, the claimed system "addresses the need for an improved microbiology validation system. **During a culture's 'testing lifecycle'** in a clinical micro-biology laboratory" (Application page 2, lines 24-29). Schaeffer teaches the use of data mining for prediction of pathogens, diagnosis or treatment **prior to** or in **the absence of culturing** the pathogen whereas the claimed system supports the identification of causative pathogens that have been recovered and isolated from patient cultures. The Schaeffer and claimed systems are fundamentally different, address different problems, and Schaeffer fails to show or suggest the claimed arrangement. Consequently, withdrawal of the Rejection of claim 17 under 35 U.S.C. 102(e) based on Schaeffer is respectfully requested.

Dependent claim 18 is considered to be patentable based on its dependence on independent claim 17. Therefore, the arguments presented above with respect to claim 17 also apply to claim 18. Thus Withdrawal of the rejection of claim 18 under 35 USC 102(e) is further respectfully requested.

CLAIM 19

Dependent claim 19 is considered to be patentable based on its dependence on claim 17. Therefore, the arguments presented above with respect to claim 17 also apply to claim 19. Claim 19 is also considered to be patentable because Schaeffer neither discloses nor suggests a system in which "said at least one display image includes display elements for displaying an alert message to a user prompting a user to enter an override command indicating whether said failure condition is to be overridden" as recited in the present claimed invention. Schaeffer in para. 0090 relied on in the Rejection on page 5 fails to show or suggest "said at least one display image includes display elements for displaying an alert message to a user prompting a user to enter an override command indicating whether said failure condition is to be overridden". Paragraph 0090 merely discusses generation of reports from a database and provides no 35 USC 112 compliant enabling disclosure of such a feature and no mention or suggestion of overriding a command at all. Consequently, withdrawal of the Rejection of claim 19 under 35 U.S.C. 102(e) based on Schaeffer is respectfully requested.

CLAIM 20

Claim 20 recites a system "for processing information related to laboratory tests and results" comprising "an interface processor for receiving user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test; a validation processor for employing one or more user

determined validation pre-conditions in comparing an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results and identifies a failure condition in response to said individual laboratory test result failing to match said corresponding expected test result; and a result processor for initiating generation of an alert message to a user indicating a failure condition of said individual test performed at a particular time stage of said different time stages." These features are not shown (or suggested) in Schaeffer.

The laboratory test result processing system of claim 20 receives "user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different stages of a laboratory test." A "validation processor" employs "one or more user determined validation pre-conditions in comparing an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results and identifies a failure condition in response to said laboratory test result failing to match said corresponding expected test result." These features are neither shown nor suggested in Schaeffer or the other references. The claimed system "addresses the need for an improved microbiology validation system. During a culture's 'testing lifecycle' in a clinical micro-biology laboratory, numerous results are entered and released over a course of hours, days or weeks." The system "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2, lines 24-29). The system advantageously performs "validations of test cultures by continuously monitoring and comparing test results as they occur with previously obtained test results throughout the lifecycle of a culture. A further advantage provided by the invention is a capability to monitor test results that are entered throughout the lifecycle of a culture. The invention also

advantageously considers specific quantities when defining expected results and alerts a user of unexpected results prior to their release to a physician for review. A still further advantage allows a user to define who can override a validation failure" (Application page 3, line 29 to page 4, line 4). The claimed features as well as associated problems addressed and advantages are not recognized or contemplated in Schaeffer.

Schaeffer does NOT show or suggest "receiving user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test" and "a validation processor for employing one or more user determined validation pre-conditions in comparing an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results and identifies a failure condition in response to said individual laboratory test result failing to match said corresponding expected test result." Schaeffer "teaches the use of data mining approaches to better predict the pathogen encountered and to provide better medical practitioner guidance with respect to the undiagnosed patient. This is particularly crucial within this application since susceptibilities and tolerance to pathogen mutations and their treatment rapidly change" (Schaeffer par. 0035). Schaeffer is concerned with the management of predicted diseases in patients with specific symptoms. The predictions are based on the historical epidemiological data such as epidemiology profiles, patient demographics and similar symptoms and are used to suggest courses of treatment. Schaeffer describes how the historical data is entered into the system (para. 0049, 0050), and how the data can be cleaned i.e. to remove patient specific identification information (para. 0072) and how the data can be retrieved and sorted (para. 0087).

Schaeffer, contrary to the Rejection statements on page 3 does not show or suggest in para. 0044 or elsewhere "receiving user entered data identifying a plurality of results

expected for a corresponding plurality of test results derived at different time stages of a laboratory test". Schaeffer in para. 0044 merely indicates "The present invention thus allows prediction, or diagnosis, for the particular patient" which "may preferably be done for the patient **prior to**, or in the **absence of**, obtaining a sample, and analyzing the sample, from the particular patient." Schaeffer in paragraph 0044 advocates prediction of diagnosis without "receiving user entered data identifying a plurality of results" and certainly provides no suggestion at all of "receiving **user entered** data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test" and "employing one or more user determined validation pre-conditions in **comparing** an individual result of said plurality of **expected** test results with a corresponding individual laboratory test result of said plurality of test results and identifies a **failure condition** in response to said individual laboratory test result failing to match said corresponding expected test result."

Applicant further respectfully disagrees with the assertion on page 9 of the Rejection that page 4 [0048] and pages 7-8 [0081] of Schaeffer describe "receiving user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test" as recited in the present claimed invention. Rather, page 4 [0048] describes the types and source of information that is taken into consideration when predicting the possible infection/disease of a patient. This information emphasizes patient demographics, but can also include results from cultures (such as Urine, throat etc.). The culture results that are being described are results that have **already been released** from the laboratory performing the tests. These results, plus the other information, are used by Schaeffer to predict a disease. The present invention, on the other hand, describes a validation processor that is utilized within the laboratory to facilitate the workflow of a technologist while performing a culture "work-up" **prior to the**

release of the results to the physician. It is not used to predict disease. It is a rules based processor that will guide and alert the user based on predefined parameters. Pages 7-8 [0081] of Schaeffer describe using probabilities, based on previously entered data, to determine conditions. The present invention, on the other hand, can be tailored by the user and utilized to the extent they desire. The processor can be programmed to utilize known patterns; it can even be utilized to "remind" the user of additional workflow steps (page 13, lines 10-14).

Schaeffer teaches data mining of historical epidemiological data may be used to predict a pathogen and does NOT suggest user entry of "data identifying a plurality of" expected results of a "laboratory test." On the contrary, the Schaeffer method is intended to be performed prior to, or in the absence of, a culture (Para. 0044) and consequently is wholly **independent** of a "laboratory test." In addition, Schaeffer in paragraphs 0052, 0056 or elsewhere does not suggest a user interface for "receiving" "user entered data" "identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test" and "employing one or more user determined validation pre-conditions in comparing an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of tests results and identifies a failure condition in response to said individual laboratory test result failing to match said corresponding expected test result." There is no mention in para. 0056 and 0074 or elsewhere in Schaeffer of a "pre-condition" at all and no suggestion of a user interface for "receiving" "user entered data" and "employing one or more user determined validation pre-conditions in **comparing** an individual result of said plurality of **expected** test results **with** a corresponding individual laboratory test result of said plurality of test results and identifies a **failure condition** in response to said individual laboratory test result failing to match said corresponding expected test result."

Applicant further respectfully disagrees with the assertion on page 10 of the Rejection stating that Schaeffer on page 7 [0071], lines 13-15 describes the present invention. This passage describes how the data is retrieved from the database. Naturally, this data must be entered somehow. Schaeffer requires the user to actively "request" or query the database to retrieve an answer. The present claimed invention, on the other hand, does not require the user to actively "request" an answer based on the rule parameters that are defined. The inventive system processor is "always on" and continuously monitors the workflow of the user. When the user initiates certain functions (ex. "result release"), the rules are triggered and if necessary, a message is displayed for the user. The inventive system comprises a workflow tool, not a database used only when a specific query is initiated as with Schaeffer.

Schaeffer in para. 0056 mentions a determination "if the identity of the antimicrobial is provided" of a "person's outcome at the completion of the course of treatment" and "whether the antimicrobial is effective for treating the identified bacterium. That is, whether the symptoms are resolved by completion of the course of antimicrobial treatment is an indicator as to whether the antimicrobial taken is effective in treating the bacterial infection." However, whether or not a course of antimicrobial treatment is effective in **treating** a patient has nothing to do with whether or not a "laboratory test result" meets user entered "pre-condition" criteria. A treatment outcome is NOT (and does not suggest) a "laboratory test result." Consequently, Schaeffer fails to suggest a user interface for "receiving" "user entered data" and "employing one or more user determined validation pre-conditions in **comparing** an individual result of said plurality of **expected** test results **with** a corresponding individual laboratory test result of said plurality of test results and identifies a **failure condition** in response to said individual laboratory test result

failing to match said corresponding expected test result." Paragraph 0074 of Schaeffer relied on in the Rejection on page 3 concerns "data cleaning" and has no bearing on "employing one or more user determined validation pre-conditions in comparing an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results."

Applicant respectfully submits that contrary to page 10 of the rejection, Schaeffer on page 8, [0086] does not describe "employing one or more user determined validation pre-conditions in comparing an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results and identifies a failure condition in response to said individual laboratory test result failing to match said corresponding expected test result" as recited in the present claimed invention. This passage of Schaeffer describes the evaluation of patterns which are used to determine the confidence level of the data. Confidence levels are required by this invention because predictions are being made based on historical data being queried. The confidence levels assist the physician in determining if the prediction should be followed, as in the case of predicting the outcome of a particular treatment on a virtual patient (Schaeffer, [091] lines 16-23). The present claimed invention, however, is based on known patterns (accepted patters that are known within the art) or known hospital procedures. The rule parameter values are defined based on these patterns or procedures. When a result or results are entered and trigger a message to display, the user knows that the pattern does not match. There is no need for confidence levels. The inventive system allows for three severity levels, which further assist the user in determining their next step.

Schaeffer in para. 0087 relied on in the Rejection on page 3 also fails to show or suggest a "result processor for initiating generation of an alert message to a user indicating

a failure condition." Paragraph 0087 merely discussed generation of reports from a database and provides no 35 USC 112 compliant enabling disclosure of "initiating generation of an alert message to a user indicating a failure condition" derived by employing "one or more user determined validation pre-conditions in **comparing** an individual result of said plurality of **expected** test results **with** a corresponding individual laboratory test result of said plurality of test results." Schaeffer is not concerned with facilitating the operation of laboratory testing or of providing a system that "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2, lines 24-29). On the contrary Schaeffer discloses a function that is performed **prior to**, or in the **absence** of, a culture (Para. 0044) and consequently is wholly **independent** of a "laboratory test".

The Schaeffer system "relates to the management of diagnosis and treatment of infections prior to or in the absence of culturing the pathogen prior to commencing treatment" (para. 0002). In contrast, the claimed system "addresses the need for an improved microbiology validation system. **During a culture's 'testing lifecycle'** in a clinical micro-biology laboratory" (Application page 2, lines 24-29). Schaeffer teaches the use of data mining for prediction of pathogens, diagnosis or treatment **prior to** or in **the absence of culturing** the pathogen whereas the claimed system supports the identification of causative pathogens that have been recovered and isolated from patient cultures. The Schaeffer and claimed systems are fundamentally different, address different problems, and Schaeffer fails to show or suggest the claimed arrangement. Consequently, withdrawal of the Rejection of claim 20 under 35 U.S.C. 102(e) based on Schaeffer is respectfully requested.

CLAIM 21

Claim 21 recites a method "for processing information related to laboratory tests and results" comprising the activities of "receiving user entered data identifying a laboratory test result of a patient specimen culture; receiving user entered data identifying an expected result of said laboratory test; employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result; identifying a failure condition in response to said laboratory test result failing to match said expected test result; and initiating generation of an alert message to a user indicating said failure condition." Schaeffer neither discloses nor suggests these features.

The laboratory test result processing system of claim 21 receives "user entered data identifying a laboratory test result of a patient specimen culture" and "user entered data identifying an expected result of said laboratory test." "Employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result" and "identifying a failure condition in response to said laboratory test result failing to match said expected test result." These features are neither shown nor suggested in Schaeffer or the other references. The claimed system "addresses the need for an improved microbiology validation system. During a culture's 'testing lifecycle' in a clinical micro-biology laboratory, numerous results are entered and released over a course of hours, days or weeks." The system "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2, lines 24-29). The system advantageously performs "validations of test cultures by continuously monitoring and comparing test results as they occur with previously obtained test results throughout the lifecycle of a culture. A further advantage

provided by the invention is a capability to monitor test results that are entered throughout the lifecycle of a culture. The invention also advantageously considers specific quantities when defining expected results and alerts a user of unexpected results prior to their release to a physician for review. A still further advantage allows a user to define who can override a validation failure" (Application page 3, line 29 to page 4, line 4). The claimed features as well as associated problems addressed and advantages are not recognized or contemplated in Schaeffer.

Schaeffer does NOT show or suggest "receiving user entered data identifying a laboratory test result of a patient specimen culture" and "receiving user entered data identifying an expected result of said laboratory test" and "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result" and "identifying a failure condition in response to said laboratory test result failing to match said expected test result." Schaeffer "teaches the use of data mining approaches to better predict the pathogen encountered and to provide better medical practitioner guidance with respect to the undiagnosed patient. This is particularly crucial within this application since susceptibilities and tolerance to pathogen mutations and their treatment rapidly change" (Schaeffer par. 0035). Schaeffer is concerned with the management of predicted diseases in patients with specific symptoms. The predictions are based on the historical epidemiological data such as epidemiology profiles, patient demographics and similar symptoms and are used to suggest courses of treatment. Schaeffer describes how the historical data is entered into the system (para. 0049, 0050), and how the data can be cleaned i.e. to remove patient specific identification information (para. 0072) and how the data can be retrieved and sorted (para. 0087).

Schaeffer, contrary to the Rejection statements on page 3 does not show or suggest in para. 0044 or elsewhere "receiving user entered data identifying a laboratory test result of a patient specimen culture" and "receiving user entered data identifying an expected result of said laboratory test." Schaeffer in para. 0044 merely indicates "The present invention thus allows prediction, or diagnosis, for the particular patient" which "may preferably be done for the patient **prior to**, or in the **absence of**, obtaining a sample, and analyzing the sample, from the particular patient." Schaeffer in paragraph 0044 advocates prediction of diagnosis without "receiving user entered data identifying a laboratory test result" and certainly provides no suggestion at all of "receiving **user entered** data identifying an expected result of said laboratory test" and "employing one or more user determined validation pre-conditions in **comparing** said laboratory test result with said **expected** test result" and "identifying a **failure condition** in response to said laboratory test result failing to match said expected test result."

Applicant further respectfully disagrees with the assertion on page 9 of the Rejection that page 4 [0048] and pages 7-8 [0081] of Schaeffer describe "receiving user entered data identifying an expected result of said laboratory test" as recited in the present claimed invention. Rather, page 4 [0048] describes the types and source of information that is taken into consideration when predicting the possible infection/disease of a patient. This information emphasizes patient demographics, but can also include results from cultures (such as Urine, throat etc.). The culture results that are being described are results that have **already been released** from the laboratory performing the tests. These results, plus the other information, are used by Schaeffer to predict a disease. The present invention, on the other hand, describes a validation processor that is utilized within the laboratory to facilitate the workflow of a technologist while performing a culture "work-up" **prior to the release** of the results to the physician. It is not used to predict disease. It

is a rules based processor that will guide and alert the user based on predefined parameters. Pages 7-8 [0081] of Schaeffer describe using probabilities, based on previously entered data, to determine conditions. The present invention, on the other hand, can be tailored by the user and utilized to the extent they desire. The processor can be programmed to utilize known patterns; it can even be utilized to "remind" the user of additional workflow steps (page 13, lines 10-14).

Schaeffer teaches data mining of historical epidemiological data may be used to predict a pathogen and does NOT suggest user entry of "data identifying an expected result" of a "laboratory test." On the contrary, the Schaeffer method is intended to be performed prior to, or in the absence of, a culture (Para. 0044) and consequently is wholly **independent** of a "laboratory test." In addition, Schaeffer in paragraphs 0052, 0056 or elsewhere does not suggest "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result" and "identifying a failure condition in response to said laboratory test result failing to match said expected test result." There is no mention in para. 0056 and 0074 or elsewhere in Schaeffer of a "pre-condition" at all and no suggestion of "employing one or more user determined validation pre-conditions in **comparing** said laboratory test result **with** said **expected** test result" and "identifying a **failure condition** in response to said laboratory test result failing to match said expected test result."

Applicant further respectfully disagrees with the assertion on page 10 of the Rejection stating that Schaeffer on page 7 [0071], lines 13-15 describes the present invention. This passage describes how the data is retrieved from the database. Naturally, this data must be entered somehow. Schaeffer requires the user to actively "request" or query the database to retrieve an answer. The present claimed invention, on the other hand,

does not require the user to actively "request" an answer based on the rule parameters that are defined. The inventive system processor is "always on" and continuously monitors the workflow of the user. When the user initiates certain functions (ex. "result release"), the rules are triggered and if necessary, a message is displayed for the user. The inventive system comprises a workflow tool, not a database used only when a specific query is initiated as with Schaeffer.

Schaeffer in para. 0056 mentions a determination "if the identity of the antimicrobial is provided" of a "person's outcome at the completion of the course of treatment" and "whether the antimicrobial is effective for treating the identified bacterium. That is, whether the symptoms are resolved by completion of the course of antimicrobial treatment is an indicator as to whether the antimicrobial taken is effective in treating the bacterial infection." However, whether or not a course of antimicrobial treatment is effective in **treating** a patient has nothing to do with whether or not a "laboratory test result" meets user entered "pre-condition" criteria. A treatment outcome is NOT (and does not suggest) a "laboratory test result." Consequently, Schaeffer fails to suggest a user interface for "receiving" "user entered data" and "employing one or more user determined validation pre-conditions in **comparing** said laboratory test result **with** said **expected** test result" and "identifying a **failure condition** in response to said laboratory test result failing to match said expected test result." Paragraph 0074 of Schaeffer relied on in the Rejection on page 3 concerns "data cleaning" and has no bearing on "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result."

Applicant respectfully submits that contrary to page 10 of the rejection, Schaeffer on page 8, [0086] does not describe "employing one or more user determined validation

pre-conditions in comparing said laboratory test result with said expected test result" and "identifying a failure condition in response to said laboratory test result failing to match said expected test result" as recited in the present claimed invention. This passage of Schaeffer describes the evaluation of patterns which are used to determine the confidence level of the data. Confidence levels are required by this invention because predictions are being made based on historical data being queried. The confidence levels assist the physician in determining if the prediction should be followed, as in the case of predicting the outcome of a particular treatment on a virtual patient (Schaeffer, [091] lines 16-23). The present claimed invention, however, is based on known patterns (accepted patters that are known within the art) or known hospital procedures. The rule parameter values are defined based on these patterns or procedures. When a result or results are entered and trigger a message to display, the user knows that the pattern does not match. There is no need for confidence levels. The inventive system allows for three severity levels, which further assist the user in determining their next step.

Schaeffer in para. 0087 relied on in the Rejection on page 3 also fails to show or suggest "initiating generation of an alert message to a user indicating a failure condition." Paragraph 0087 merely discussed generation of reports from a database and provides no 35 USC 112 compliant enabling disclosure of "initiating generation of an alert message to a user indicating a failure condition" derived by "employing one or more user determined validation pre-conditions in **comparing** said laboratory test result **with** said **expected** test result." Schaeffer is not concerned with facilitating the operation of laboratory testing or of providing a system that "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2, lines 24-29). On the contrary Schaeffer discloses a function that is performed **prior to**,

or in the **absence** of, a culture (Para. 0044) and consequently is wholly **independent** of a "laboratory test".

The Schaeffer system "relates to the management of diagnosis and treatment of infections prior to or in the absence of culturing the pathogen prior to commencing treatment" (para. 0002). In contrast, the claimed system "addresses the need for an improved microbiology validation system. **During a culture's 'testing lifecycle'** in a clinical micro-biology laboratory" (Application page 2, lines 24-29). Schaeffer teaches the use of data mining for prediction of pathogens, diagnosis or treatment **prior to** or in **the absence of culturing** the pathogen whereas the claimed system supports the identification of causative pathogens that have been recovered and isolated from patient cultures. The Schaeffer and claimed systems are fundamentally different, address different problems, and Schaeffer fails to show or suggest the claimed arrangement. Consequently, withdrawal of the Rejection of claim 21 under 35 U.S.C. 102(e) based on Schaeffer is respectfully requested.

CLAIM 22

Claim 22 recites a method "for processing information related to laboratory tests and results" comprising the activities of "receiving user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test; employing one or more user determined validation pre-conditions in comparing an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results; identifying a failure condition in response to said individual laboratory test result failing to match said corresponding expected test result; and initiating generation of an alert message to a user

indicating a failure condition of said individual test performed at a particular time stage of said different time stages." These features are neither disclosed nor suggested in Schaeffer.

The laboratory test result processing method of claim 22 comprises "receiving user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test." "Employing one or more user determined validation pre-conditions in comparing an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results" and "identifying a failure condition in response to said individual laboratory test result failing to match said corresponding expected test result." These features are neither shown nor suggested in Schaeffer or the other references. The claimed system "addresses the need for an improved microbiology validation system. During a culture's 'testing lifecycle' in a clinical micro-biology laboratory, numerous results are entered and released over a course of hours, days or weeks." The system "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2, lines 24-29). The system advantageously performs "validations of test cultures by continuously monitoring and comparing test results as they occur with previously obtained test results throughout the lifecycle of a culture. A further advantage provided by the invention is a capability to monitor test results that are entered throughout the lifecycle of a culture. The invention also advantageously considers specific quantities when defining expected results and alerts a user of unexpected results prior to their release to a physician for review. A still further advantage allows a user to define who can override a validation failure" (Application page 3, line 29 to page 4, line 4). The claimed features as well as associated problems addressed and advantages are not recognized or contemplated in Schaeffer.

Schaeffer does NOT show or suggest "receiving user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test" and "employing one or more user determined validation pre-conditions in comparing an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results" and "identifying a failure condition in response to said individual laboratory test result failing to match said corresponding expected test result." Schaeffer "teaches the use of data mining approaches to better predict the pathogen encountered and to provide better medical practitioner guidance with respect to the undiagnosed patient. This is particularly crucial within this application since susceptibilities and tolerance to pathogen mutations and their treatment rapidly change" (Schaeffer par. 0035). Schaeffer is concerned with the management of predicted diseases in patients with specific symptoms. The predictions are based on the historical epidemiological data such as epidemiology profiles, patient demographics and similar symptoms and are used to suggest courses of treatment. Schaeffer describes how the historical data is entered into the system (para. 0049, 0050), and how the data can be cleaned i.e. to remove patient specific identification information (para. 0072) and how the data can be retrieved and sorted (para. 0087).

Schaeffer, contrary to the Rejection statements on page 3 does not show or suggest in para. 0044 or elsewhere "receiving user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test." Schaeffer in para. 0044 merely indicates "The present invention thus allows prediction, or diagnosis, for the particular patient" which "may preferably be done for the patient **prior to**, or in the **absence of**, obtaining a sample, and analyzing the sample, from the particular patient." Schaeffer in paragraph 0044 advocates prediction of diagnosis

without "receiving user entered data identifying a laboratory test result" and certainly provides no suggestion at all of "receiving **user entered** data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test" and "employing one or more user determined validation pre-conditions in **comparing** an individual result of said plurality of **expected** test results with a corresponding individual laboratory test result of said plurality of test results" and "identifying a **failure condition** in response to said individual laboratory test result failing to match said corresponding expected test result."

Applicant further respectfully disagrees with the assertion on page 9 of the Rejection that page 4 [0048] and pages 7-8 [0081] of Schaeffer describe "receiving user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test" as recited in the present claimed invention. Rather, page 4 [0048] describes the types and source of information that is taken into consideration when predicting the possible infection/disease of a patient. This information emphasizes patient demographics, but can also include results from cultures (such as Urine, throat etc.). The culture results that are being described are results that have **already been released** from the laboratory performing the tests. These results, plus the other information, are used by Schaeffer to predict a disease. The present invention, on the other hand, describes facilitating the workflow within a laboratory of a technologist while performing a culture "work-up" **prior to the release** of the results to the physician. It is not used to predict disease. It is a rules based processor that will guide and alert the user based on predefined parameters. Pages 7-8 [0081] of Schaeffer describe using probabilities, based on previously entered data, to determine conditions. The present invention, on the other hand, can be tailored by the user and utilized to the extent they

desire. The processor can be programmed to utilize known patterns; it can even be utilized to "remind" the user of additional workflow steps (page 13, lines 10-14).

Schaeffer teaches data mining of historical epidemiological data may be used to predict a pathogen and does NOT suggest user entry of "data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test." On the contrary, the Schaeffer method is intended to be performed prior to, or in the absence of, a culture (Para. 0044) and consequently is wholly **independent** of a "laboratory test." In addition, Schaeffer in paragraphs 0052, 0056 or elsewhere does not suggest a user interface for "receiving" "user entered data" and "employing one or more user determined validation pre-conditions in comparing an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results" and "identifying a failure condition in response to said individual laboratory test result failing to match said corresponding expected test result." There is no mention in para. 0056 and 0074 or elsewhere in Schaeffer of a "pre-condition" at all and no suggestion of a user interface for "receiving" "user entered data" and "employing one or more user determined validation pre-conditions in **comparing** an individual result of said plurality of **expected** test results **with** a corresponding individual laboratory test result of said plurality of test results" and "identifying a **failure condition** in response to said individual laboratory test result failing to match said corresponding expected test result."

Applicant further respectfully disagrees with the assertion on page 10 of the Rejection stating that Schaeffer on page 7 [0071], lines 13-15 describes the present invention. This passage describes how the data is retrieved from the database. Naturally, this data must be entered somehow. Schaeffer requires the user to actively "request" or

query the database to retrieve an answer. The present claimed invention, on the other hand, does not require the user to actively "request" an answer based on the rule parameters that are defined. The inventive system processor is "always on" and continuously monitors the workflow of the user. When the user initiates certain functions (ex. "result release"), the rules are triggered and if necessary, a message is displayed for the user. The inventive system comprises a workflow tool, not a database used only when a specific query is initiated as with Schaeffer.

Schaeffer in para. 0056 mentions a determination "if the identity of the antimicrobial is provided" of a "person's outcome at the completion of the course of treatment" and "whether the antimicrobial is effective for treating the identified bacterium. That is, whether the symptoms are resolved by completion of the course of antimicrobial treatment is an indicator as to whether the antimicrobial taken is effective in treating the bacterial infection." However, whether or not a course of antimicrobial treatment is effective in **treating** a patient has nothing to do with whether or not a "laboratory test result" meets user entered "pre-condition" criteria. A treatment outcome is NOT (and does not suggest) a "laboratory test result." Consequently, Schaeffer fails to suggest a user interface for "receiving" "user entered data" and "employing one or more user determined validation pre-conditions in **comparing** an individual result of said plurality of **expected** test results **with** a corresponding individual laboratory test result of said plurality of test results" and "identifying a **failure condition** in response to said individual laboratory test result failing to match said corresponding expected test result." Paragraph 0074 of Schaeffer relied on in the Rejection on page 3 concerns "data cleaning" and has no bearing on "employing one or more user determined validation pre-conditions in comparing an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results."

Applicant respectfully submits that contrary to page 10 of the rejection, Schaeffer on page 8, [0086] does not describe "employing one or more user determined validation pre-conditions in comparing an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results" and "identifying a failure condition in response to said individual laboratory test result failing to match said corresponding expected test result" as recited in the present claimed invention. This passage of Schaeffer describes the evaluation of patterns which are used to determine the confidence level of the data. This is required by this invention because predictions are being made based on historical data being queried. The confidence levels assist the physician in determining if the prediction should be followed, as in the case of predicting the outcome of a particular treatment on a virtual patient (Schaeffer, [091] lines 16-23). The present claimed invention, however, is based on known patterns (accepted patters that are known within the art) or known hospital procedures. The rule parameter values are defined based on these patterns or procedures. When a result or results are entered and trigger a message to display, the user knows that the pattern does not match. There is no need for confidence levels. The inventive system allows for three severity levels, which further assist the user in determining their next step.

Schaeffer in para. 0087 relied on in the Rejection on page 3 also fails to show or suggest "initiating generation of an alert message to a user indicating a failure condition." Paragraph 0087 merely discussed generation of reports from a database and provides no 35 USC 112 compliant enabling disclosure of "initiating generation of an alert message to a user indicating a failure condition" derived by "employing one or more user determined validation pre-conditions in **comparing** an individual result of said plurality of **expected** test results **with** a corresponding individual laboratory test result of said plurality of test

results." Schaeffer is not concerned with facilitating the operation of laboratory testing or of providing a system that "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2, lines 24-29). On the contrary Schaeffer discloses a function that is performed **prior to**, or in the **absence** of, a culture (Para. 0044) and consequently is wholly **independent** of a "laboratory test".

The Schaeffer system "relates to the management of diagnosis and treatment of infections prior to or in the absence of culturing the pathogen prior to commencing treatment" (para. 0002). In contrast, the claimed system "addresses the need for an improved microbiology validation system. **During a culture's 'testing lifecycle'** in a clinical micro-biology laboratory" (Application page 2, lines 24-29). Schaeffer teaches the use of data mining for prediction of pathogens, diagnosis or treatment **prior to** or in **the absence of culturing** the pathogen whereas the claimed system supports the identification of causative pathogens that have been recovered and isolated from patient cultures. The Schaeffer and claimed systems are fundamentally different, address different problems, and Schaeffer fails to show or suggest the claimed arrangement. Consequently, withdrawal of the Rejection of claim 22 under 35 U.S.C. 102(e) based on Schaeffer is respectfully requested.

CLAIM 23

Claim 23 recites a system for "processing information related to laboratory tests and results" comprising "a display processor for initiating generation of at least one display image including display elements for, enabling a user to enter data identifying an expected laboratory test result, a laboratory test result; at least one further expected laboratory test

result, at least one further laboratory test result; and a plurality of validation pre-conditions for validating said first laboratory test, and for displaying an alert message to a user indicating a failure condition." The failure condition is derived by "employing one or more user determined validation pre-conditions in comparing said expected laboratory test result with said laboratory test result and identifying a first failure condition in response to said laboratory test result failing to match said expected laboratory test result; comparing said at least one further laboratory test result with said at least one further expected laboratory test result and identifying a second failure condition in response to said at least one further laboratory test result failing to match said at least one further expected laboratory test result." The plurality of validation pre-conditions is also for "determining that at least one of said plurality of validation pre-conditions are not satisfied." These features are neither disclosed nor suggested in Schaeffer.

The laboratory test result processing system of claim 23 enables "a user to enter data identifying an expected laboratory test result, a laboratory test result; at least one further expected laboratory test result, at lest one further laboratory test result; and a plurality of validation pre-conditions for validating said first laboratory test." "Employing one or more user determined validation pre-conditions in comparing said expected laboratory test result with the said laboratory test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result." These features are neither shown nor suggested in Schaeffer or the other references. The claimed system "addresses the need for an improved microbiology validation system. During a culture's 'testing lifecycle' in a clinical micro-biology laboratory, numerous results are entered and released over a course of hours, days or weeks." The system "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that

inconsistent or wrong results are not released to a physician for review" (Application page 2, lines 24-29). The system advantageously performs "validations of test cultures by continuously monitoring and comparing test results as they occur with previously obtained test results throughout the lifecycle of a culture. A further advantage provided by the invention is a capability to monitor test results that are entered throughout the lifecycle of a culture. The invention also advantageously considers specific quantities when defining expected results and alerts a user of unexpected results prior to their release to a physician for review. A still further advantage allows a user to define who can override a validation failure" (Application page 3, line 29 to page 4, line 4). The claimed features as well as associated problems addressed and advantages are not recognized or contemplated in Schaeffer.

Schaeffer does NOT show or suggest "enabling a user to enter data identifying an expected laboratory test result, a laboratory test result; at least one further expected laboratory test result, at least one further laboratory test result; and a plurality of validation pre-conditions for validating said first laboratory test" and "employing one or more user determined validation pre-conditions in comparing said expected laboratory test result with said laboratory test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result." Schaeffer "teaches the use of data mining approaches to better predict the pathogen encountered and to provide better medical practitioner guidance with respect to the undiagnosed patient. This is particularly crucial within this application since susceptibilities and tolerance to pathogen mutations and their treatment rapidly change" (Schaeffer par. 0035). Schaeffer is concerned with the management of predicted diseases in patients with specific symptoms. The predictions are based on the historical epidemiological data such as epidemiology profiles, patient demographics and similar symptoms and are used to suggest courses of treatment.

Schaeffer describes how the historical data is entered into the system (para. 0049, 0050), and how the data can be cleaned i.e. to remove patient specific identification information (para. 0072) and how the data can be retrieved and sorted (para. 0087).

Schaeffer, contrary to the Rejection statements on page 3 does not show or suggest in para. 0044 or elsewhere "enabling a user to enter data identifying an expected laboratory test result, a laboratory test result; at least one further expected laboratory test result, at least one further laboratory test result; and a plurality of validation pre-conditions for validating said first laboratory test." Schaeffer in para. 0044 merely indicates "The present invention thus allows prediction, or diagnosis, for the particular patient" which "may preferably be done for the patient **prior to**, or in the **absence of**, obtaining a sample, and analyzing the sample, from the particular patient." Schaeffer in paragraph 0044 advocates prediction of diagnosis without "enabling a user to enter data identifying an expected laboratory test result, a laboratory test result; at least one further expected laboratory test result, at least one further laboratory test result" and certainly provides no suggestion at all of "enabling a **user to enter** data identifying...a plurality of validation pre-conditions for validating said first laboratory test" and "employing one or more user determined validation pre-conditions in **comparing** said **expected** laboratory test result with said laboratory test result and identifying a **first failure condition** in response to said laboratory test result failing to match said expected laboratory test result."

Applicant further respectfully disagrees with the assertion on page 9 of the Rejection that page 4 [0048] and pages 7-8 [0081] of Schaeffer describe "enabling a user to enter data identifying an expected laboratory test result, a laboratory test result; at least one further expected laboratory test result, at least one further laboratory test result; and a plurality of validation pre-conditions for validating said first laboratory test" as recited in

the present claimed invention. Rather, page 4 [0048] describes the types and source of information that is taken into consideration when predicting the possible infection/disease of a patient. This information emphasizes patient demographics, but can also include results from cultures (such as Urine, throat etc.). The culture results that are being described are results that have **already been released** from the laboratory performing the tests. These results, plus the other information, are used by Schaeffer to predict a disease. The present invention, on the other hand, describes a validation processor that is utilized within the laboratory to facilitate the workflow of a technologist while performing a culture "work-up" **prior to the release** of the results to the physician. It is not used to predict disease. It is a rules based processor that will guide and alert the user based on predefined parameters. Pages 7-8 [0081] of Schaeffer describe using probabilities, based on previously entered data, to determine conditions. The present invention, on the other hand, can be tailored by the user and utilized to the extent they desire. The processor can be programmed to utilize known patterns; it can even be utilized to "remind" the user of additional workflow steps (page 13, lines 10-14).

Schaeffer teaches data mining of historical epidemiological data may be used to predict a pathogen and does NOT suggest user entry of "data identifying an expected laboratory test result, a laboratory test result." On the contrary, the Schaeffer method is intended to be performed prior to, or in the absence of, a culture (Para. 0044) and consequently is wholly **independent** of a "laboratory test." In addition, Schaeffer in paragraphs 0052, 0056 or elsewhere does not suggest a user interface for "enabling a user to enter data identifying...a plurality of validation pre-conditions for validating said first laboratory test" and "employing one or more user determined validation pre-conditions in comparing said expected laboratory test result with said laboratory test result and identifying a first failure condition in response to said laboratory test result failing to match

said expected laboratory test result." There is no mention in para. 0056 and 0074 or elsewhere in Schaeffer of a "pre-condition" at all and no suggestion of a user interface for "enabling a user to enter data identifying...a plurality of validation pre-conditions for validating said first laboratory test" and "employing one or more user determined validation pre-conditions in **comparing** said **expected** laboratory test result **with** said laboratory test result and identifying a **first failure condition** in response to said laboratory test result failing to match said expected laboratory test result."

Applicant further respectfully disagrees with the assertion on page 10 of the Rejection stating that Schaeffer on page 7 [0071], lines 13-15 describes the present invention. This passage describes how the data is retrieved from the database. Naturally, this data must be entered somehow. Schaeffer requires the user to actively "request" or query the database to retrieve an answer. The present claimed invention, on the other hand, does not require the user to actively "request" an answer based on the rule parameters that are defined. The inventive system processor is "always on" and continuously monitors the workflow of the user. When the user initiates certain functions (ex. "result release"), the rules are triggered and if necessary, a message is displayed for the user. The inventive system comprises a workflow tool, not a database used only when a specific query is initiated as with Schaeffer.

Schaeffer in para. 0056 mentions a determination "if the identity of the antimicrobial is provided" of a "person's outcome at the completion of the course of treatment" and "whether the antimicrobial is effective for treating the identified bacterium. That is, whether the symptoms are resolved by completion of the course of antimicrobial treatment is an indicator as to whether the antimicrobial taken is effective in treating the bacterial infection." However, whether or not a course of antimicrobial treatment is

effective in **treating** a patient has nothing to do with whether or not a "laboratory test result" meets user entered "pre-condition" criteria. A treatment outcome is NOT (and does not suggest) a "laboratory test result." Consequently, Schaeffer fails to suggest a user interface for ""enabling a user to enter data identifying...a plurality of validation pre-conditions for validating said first laboratory test" and "employing one or more user determined validation pre-conditions in **comparing** said **expected** laboratory test result **with** said laboratory test result and identifying a **first failure condition** in response to said laboratory test result failing to match said expected laboratory test result.". Paragraph 0074 of Schaeffer relied on in the Rejection on page 3 concerns "data cleaning" and has no bearing on "employing one or more user determined validation pre-conditions in **comparing** said **expected** laboratory test result **with** said laboratory test result."

Applicant respectfully submits that contrary to page 10 of the rejection, Schaeffer on page 8, [0086] does not describe "employing one or more user determined validation pre-conditions in comparing said expected laboratory test result with said laboratory test result and identifying a first failure condition in response to said laboratory test result failing to match said expected laboratory test result" as recited in the present claimed invention. Nor does this passage, or elsewhere in Schaeffer, describe "comparing said at least one further laboratory test result with said at least one further expected laboratory test result and identifying a second failure condition in response to said at least one further laboratory test result failing to match said at least one further expected laboratory test result" as recited in the present invention. Rather, this passage of Schaeffer describes the evaluation of patterns which are used to determine the confidence level of the data. Confidence levels are required by this invention because predictions are being made based on historical data being queried. The confidence levels assist the physician in determining if the prediction should be followed, as in the case of predicting the outcome of a particular

treatment on a virtual patient (Schaeffer, [091] lines 16-23). The present claimed invention, however, is based on known patterns (accepted patters that are known within the art) or known hospital procedures. The rule parameter values are defined based on these patterns or procedures. When a result or results are entered and trigger a message to display, the user knows that the pattern does not match. There is no need for confidence levels. The inventive system allows for three severity levels, which further assist the user in determining their next step.

The Schaeffer system "relates to the management of diagnosis and treatment of infections prior to or in the absence of culturing the pathogen prior to commencing treatment" (para. 0002). In contrast, the claimed system "addresses the need for an improved microbiology validation system. **During a culture's 'testing lifecycle'** in a clinical micro-biology laboratory" (Application page 2, lines 24-29). Schaeffer teaches the use of data mining for prediction of pathogens, diagnosis or treatment **prior to** or in **the absence of culturing** the pathogen whereas the claimed system supports the identification of causative pathogens that have been recovered and isolated from patient cultures. The Schaeffer and claimed systems are fundamentally different, address different problems, and Schaeffer fails to show or suggest the claimed arrangement. Consequently, withdrawal of the Rejection of claim 23 under 35 U.S.C. 102(e) based on Schaeffer is respectfully requested.

CLAIMS 24 and 25

Claim 24 recites a method "for processing information related to laboratory tests and results" comprising the steps of "a) receiving user entered data comprising: an expected first laboratory test result of a first laboratory test requiring validation processing; an actual first laboratory test result; at least one further expected laboratory test result of at

least one further laboratory test for validating said first laboratory test; and at least one further actual laboratory test result of said at least one further laboratory test; and a plurality of validation preconditions; b) employing one or more user determined validation pre-conditions in comparing said expected first laboratory test result with said actual first laboratory test result and identifying a first failure condition in response to said expected first laboratory test result failing to match said actual first laboratory test result; c) comparing said at least one further expected laboratory test result with said at least one further actual laboratory test result and identifying a second failure condition in response to said at least one further expected laboratory test result failing to match said at least one further actual laboratory test result; and d) identifying a third failure condition when said plurality of validation pre-conditions are not satisfied." These features are neither disclosed nor suggested in Schaeffer.

The laboratory test result processing system of claim 24 receives "user entered data comprising an expected first laboratory test result of a first laboratory test requiring validation processing; an actual first laboratory test result; at least one further expected laboratory test result of at least one further laboratory test for validating said first laboratory test; and at least one further actual laboratory test result of said at least one further laboratory test; and a plurality of validation pre-conditions." A further step includes "employing one or more user determined validation pre-conditions in comparing said expected first laboratory test result with said actual first laboratory test result" and "identifying a first failure condition in response to said expected first laboratory test result failing to match said actual first laboratory test result." These features are neither shown nor suggested in Schaeffer or the other references. The claimed system "addresses the need for an improved microbiology validation system. During a culture's 'testing lifecycle' in a clinical micro-biology laboratory, numerous results are entered and released over a course

of hours, days or weeks." The system "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2, lines 24-29). The system advantageously performs "validations of test cultures by continuously monitoring and comparing test results as they occur with previously obtained test results throughout the lifecycle of a culture. A further advantage provided by the invention is a capability to monitor test results that are entered throughout the lifecycle of a culture. The invention also advantageously considers specific quantities when defining expected results and alerts a user of unexpected results prior to their release to a physician for review. A still further advantage allows a user to define who can override a validation failure" (Application page 3, line 29 to page 4, line 4). The claimed features as well as associated problems addressed and advantages are not recognized or contemplated in Schaeffer.

Schaeffer does NOT show or suggest "receiving user entered data comprising an expected first laboratory test result of a first laboratory test requiring validation processing; an actual first laboratory test result; at least one further expected laboratory test result of at least one further laboratory test for validating said first laboratory test; and at least one further actual laboratory test result of said at least one further laboratory test; and a plurality of validation pre-conditions" and "employing one or more user determined validation pre-conditions in comparing said expected first laboratory test result with said actual first laboratory test result and identifying a first failure condition in response to said expected first laboratory test result failing to match said actual first laboratory test result." Schaeffer "teaches the use of data mining approaches to better predict the pathogen encountered and to provide better medical practitioner guidance with respect to the undiagnosed patient. This is particularly crucial within this application since

susceptibilities and tolerance to pathogen mutations and their treatment rapidly change" (Schaeffer par. 0035). Schaeffer is concerned with the management of predicted diseases in patients with specific symptoms. The predictions are based on the historical epidemiological data such as epidemiology profiles, patient demographics and similar symptoms and are used to suggest courses of treatment. Schaeffer describes how the historical data is entered into the system (para. 0049, 0050), and how the data can be cleaned i.e. to remove patient specific identification information (para. 0072) and how the data can be retrieved and sorted (para. 0087).

Schaeffer, contrary to the Rejection statements on page 3 does not show or suggest in para. 0044 or elsewhere "receiving user entered data comprising an expected first laboratory test result of a first laboratory test requiring validation processing; an actual first laboratory test result; at least one further expected laboratory test result of at least one further laboratory test for validating said first laboratory test; and at least one further actual laboratory test result of said at least one further laboratory test; and a plurality of validation pre-conditions." Schaeffer in para. 0044 merely indicates "The present invention thus allows prediction, or diagnosis, for the particular patient" which "may preferably be done for the patient **prior to**, or in the **absence of**, obtaining a sample, and analyzing the sample, from the particular patient." Schaeffer in paragraph 0044 advocates prediction of diagnosis without "receiving user entered data comprising an expected first laboratory test result of a first laboratory test requiring validation processing" and certainly provides no suggestion at all of "receiving **user entered** data comprising an actual first laboratory test result; at least one further expected laboratory test result of at least one further laboratory test for validating said first laboratory test; and at least one further actual laboratory test result of said at least one further laboratory test; and a plurality of validation pre-conditions" and "employing one or more user determined validation pre-conditions in **comparing** said

expected first laboratory test result with said **actual** first laboratory test result and identifying a **first failure condition** in response to said expected first laboratory test result failing to match said actual first laboratory test result."

Applicant further respectfully disagrees with the assertion on page 9 of the Rejection that page 4 [0048] and pages 7-8 [0081] of Schaeffer describe "receiving user entered data comprising an expected first laboratory test result of a first laboratory test requiring validation processing...and a plurality of validation pre-conditions" as recited in the present claimed invention. Rather, page 4 [0048] describes the types and source of information that is taken into consideration when predicting the possible infection/disease of a patient. This information emphasizes patient demographics, but can also include results from cultures (such as Urine, throat etc.). The culture results that are being described are results that have **already been released** from the laboratory performing the tests. These results, plus the other information, are used by Schaeffer to predict a disease. The present invention, on the other hand, describes facilitating the workflow in a laboratory of a technologist while performing a culture "work-up" **prior to the release** of the results to the physician. It is not used to predict disease. It is a rules based processor that will guide and alert the user based on predefined parameters. Pages 7-8 [0081] of Schaeffer describe using probabilities, based on previously entered data, to determine conditions. The present invention, on the other hand, can be tailored by the user and utilized to the extent they desire. The processor can be programmed to utilize known patterns; it can even be utilized to "remind" the user of additional workflow steps (page 13, lines 10-14).

Schaeffer teaches data mining of historical epidemiological data may be used to predict a pathogen and does NOT suggest user entry of "data identifying an expected first laboratory test result" of a "first laboratory test." On the contrary, the Schaeffer method is

intended to be performed prior to, or in the absence of, a culture (Para. 0044) and consequently is wholly **independent** of a "laboratory test." In addition, Schaeffer in paragraphs 0052, 0056 or elsewhere does not suggest a user interface for "receiving user entered data comprising" "a plurality of validation pre-condition" and "employing one or more user determined validation pre-conditions in comparing said expected first laboratory test result with said actual first laboratory test result and identifying a first failure condition in response to said expected first laboratory test result failing to match said actual first laboratory test result." There is no mention in para. 0056 and 0074 or elsewhere in Schaeffer of a "pre-condition" at all and no suggestion of a user interface for "receiving user entered data identifying" "a plurality of validation pre-conditions" and "employing one or more user determined validation pre-conditions in **comparing** said expected first laboratory test result **with** said **actual** first laboratory test result and identifying a **first failure condition** in response to said expected first laboratory test result failing to match said actual first laboratory test result."

Applicant further respectfully disagrees with the assertion on page 10 of the Rejection stating that Schaeffer on page 7 [0071], lines 13-15 describes the present invention. This passage describes how the data is retrieved from the database. Naturally, this data must be entered somehow. Schaeffer requires the user to actively "request" or query the database to retrieve an answer. The present claimed invention, on the other hand, does not require the user to actively "request" an answer based on the rule parameters that are defined. The inventive system processor is "always on" and continuously monitors the workflow of the user. When the user initiates certain functions (ex. "result release"), the rules are triggered and if necessary, a message is displayed for the user. The inventive system comprises a workflow tool, not a database used only when a specific query is initiated as with Schaeffer.

Schaeffer in para. 0056 mentions a determination "if the identity of the antimicrobial is provided" of a "person's outcome at the completion of the course of treatment" and "whether the antimicrobial is effective for treating the identified bacterium. That is, whether the symptoms are resolved by completion of the course of antimicrobial treatment is an indicator as to whether the antimicrobial taken is effective in treating the bacterial infection." However, whether or not a course of antimicrobial treatment is effective in **treating** a patient has nothing to do with whether or not a "laboratory test result" meets user entered "pre-condition" criteria. A treatment outcome is NOT (and does not suggest) a "laboratory test result." Consequently, Schaeffer fails to suggest a user interface for "receiving" "user entered data comprising" "a plurality of validation pre-conditions" and "employing one or more user determined validation pre-conditions in **comparing** said **expected** first laboratory test result **with** said **actual** first laboratory test result and identifying a **first failure condition** in response to said expected first laboratory test result failing to match said actual first laboratory test result." Paragraph 0074 of Schaeffer relied on in the Rejection on page 3 concerns "data cleaning" and has no bearing on "employing one or more user determined validation pre-conditions in comparing said expected first laboratory test result with said actual first laboratory test result."

Applicant respectfully submits that contrary to page 10 of the rejection, Schaeffer on page 8, [0086] does not describe "employing one or more user determined validation pre-conditions in comparing said expected first laboratory test result with said actual first laboratory test result and identifying a first failure condition in response to said expected first laboratory test result failing to match said actual first laboratory test result" as recited in the present claimed invention. This passage of Schaeffer describes the evaluation of patterns which are used to determine the confidence level of the data. This is required by

this invention because predictions are being made based on historical data being queried. The confidence levels assist the physician in determining if the prediction should be followed, as in the case of predicting the outcome of a particular treatment on a virtual patient (Schaeffer, [091] lines 16-23). The present claimed invention, however, is based on known patterns (accepted patters that are known within the art) or known hospital procedures. The rule parameter values are defined based on these patterns or procedures. When a result or results are entered and trigger a message to display, the user knows that the pattern does not match. There is no need for confidence levels. The inventive system allows for three severity levels, which further assist the user in determining their next step.

The Schaeffer system "relates to the management of diagnosis and treatment of infections prior to or in the absence of culturing the pathogen prior to commencing treatment" (para. 0002). In contrast, the claimed system "addresses the need for an improved microbiology validation system. **During a culture's 'testing lifecycle'** in a clinical micro-biology laboratory" (Application page 2, lines 24-29). Schaeffer teaches the use of data mining for prediction of pathogens, diagnosis or treatment **prior to** or in **the absence of culturing** the pathogen whereas the claimed system supports the identification of causative pathogens that have been recovered and isolated from patient cultures. The Schaeffer and claimed systems are fundamentally different, address different problems, and Schaeffer fails to show or suggest the claimed arrangement. Consequently, withdrawal of the Rejection of claim 24 under 35 U.S.C. 102(e) based on Schaeffer is respectfully requested.

Dependent claim 25 is considered to be patentable based on its dependence on independent claim 24. Therefore, the arguments presented above with respect to claim 24 also apply to claim 25. Thus Withdrawal of the rejection of claim 25 under 35 USC 102(e) is further respectfully requested.

Rejection of Claims 6 and 8 under 35 USC 103(a) over Schaeffer et al. (U.S. Patent Application 2002/0107641) in view of Peck (U.S. 5,789,173)

Reversal of the rejection of claims 6 and 8 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application 2002/0107641 issued to Schaeffer in view of U.S. Patent 5,789,173 issued to Peck is respectfully requested because the rejection makes crucial errors in interpreting the cited references. The rejection erroneously states that claims 6 and 8 are made unpatentable by Schaeffer in view of Peck.

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the examiner to establish a factual basis to support the legal conclusion of obviousness. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed.Cir. 1988). In so doing, the Examiner is expected to make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (CCPA 1966), and to provide a reason why one having ordinary skill in the pertinent art would have been led to modify the prior art or to combine prior art references to arrive at the claimed invention. Such reason must stem from some teaching, suggestion, or implication in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed.Cir. 1988), *cert. denied*, 488 U.S. 825 (1988); *Ashland Oil Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 28, 293, 227 USPQ 657, 664 (Fed.Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986); *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed.Cir. 1984). These showings by the Examiner are an

essential part of complying with the burden of presenting a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed.Cir. 1992).

CLAIM 6

Claim 6 is considered to be patentable based on its dependence on claim 1 and 5. Claim 6 is also considered to be patentable because Schaeffer and Peck, individually or in combination, neither show nor suggest the combination of features of claim 6 in which "said quantity identifier identifies a qualitative range of said quantity of microbes per unit area, including at least one of, (a) an identifier indicating "few" and (b) an identifier indicating "many".

Neither Schaeffer nor Peck alone or together, show or suggest a user interface for "receiving" "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in **comparing** said laboratory test result **with** said **expected** test result and identifying a **first failure condition** in response to said laboratory test result failing to match said expected test result". Schaeffer, as recognized in the Rejection, fails to show or suggest "a qualitative range of said quantity of microbes per unit area, including at least one of, (a) an identifier indicating "few" and (b) an identifier indicating "many"". However, contrary, to the Rejection statement on page 6, Peck in column 3 lines 35-46 merely states that bacterial and inoculation concentrations may vary. Peck (with Schaeffer) fails to suggest employing "user entered data identifying an expected result of said laboratory test" that comprises "a quantity identifier" identifying "a qualitative range" comprising a "quantity of microbes per unit area, including at least one of, (a) an identifier indicating "few" and (b) an identifier indicating "many"". The "detectable amounts of bacteria" in para. 0053 of Schaeffer relied upon in the Rejection in

connection with claim 5 and the varying inoculation concentrations of Peck fail to suggest employing "user entered data identifying an expected result of said laboratory test" that "comprises a **quantity identifier"** identifying "a qualitative range" comprising a "quantity of microbes per unit area, including at least one of, (a) an identifier indicating "few" and (b) an identifier indicating "many"". No such "quantity identifier" for use in entering an expected **laboratory test** result via a laboratory test system user interface is suggested in Schaeffer or Peck, alone or together.

Further, employing the Peck varying bacterial and inoculation concentration in Schaeffer results in a system using data mining approaches to better predict the pathogen encountered and to provide better medical practitioner guidance with respect to the undiagnosed patient based on the historical epidemiological data such as epidemiology profiles, patient demographics, data indicating varying bacterial and inoculation concentrations and similar symptoms and are used to suggest courses of treatment. Such a system fails to show or suggest a user interface for "receiving" "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in **comparing** said laboratory test result **with** said **expected** test result and identifying a **first failure condition** in response to said laboratory test result failing to match said expected test result". Also, since Schaeffer and Peck, alone or together, fail to recognize or address the specific problem of facilitating the operation of laboratory testing or of providing a system that "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2 lines 24-29), neither Schaeffer nor Peck contain any motivation or other reason for incorporating the features of the claimed arrangement. The Schaeffer with Peck system is entirely separate and independent from a laboratory test

system and user interface. Consequently, withdrawal of the rejection of claim 6 under 35 USC 103(a) is respectfully requested.

CLAIM 8

Dependent claim 8 is considered to be patentable based on its dependence on claim 1, and for reasons given in connection with claims 1 and 6. Claim 8 is also considered to be patentable because Schaeffer and Peck, individually or in combination, do not show (or suggest) the combination of features of claim 8 in which "said received user entered data identifying an expected result of said laboratory test identifies at least one of, (a) a count value of number of microbes present per unit area of a culture, (b) a color of a microbe indicator, (c) a color change of a microbe indicator."

Neither Schaeffer nor peck alone or together, show or suggest a user interface for "receiving" "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in **comparing** said laboratory test result **with** said **expected** test result and identifying a **first failure condition** in response to said laboratory test result failing to match said expected test result". Schaeffer, as recognized in the Rejection, fails to show or suggest "an expected result of said laboratory test identifies at least one of, (a) a count value of number of microbes present per unit area of a culture, (b) a color of a microbe indicator, (c) a color change of a microbe indicator". However, contrary, to the Rejection statement on page 7, Peck in column 3 lines 18-34 merely states that bacterial and inoculation concentrations may vary. Peck (with Schaeffer) fails to suggest use of user entered data indicating "an expected result of said laboratory test" that "identifies...a count value of number of microbes present per unit area of a culture". Neither Peck nor Schaeffer suggest use of user entered data indicating such "an

expected result of said laboratory test". Also, since Schaeffer and Peck, alone or together, fail to recognize or address the specific problem of facilitating the operation of laboratory testing or of providing a system that "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2 lines 24-29), neither Schaeffer nor Peck contain any motivation or other reason for incorporating the features of the claimed arrangement. Consequently, withdrawal of the rejection of claim 8 under 35 USC 103(a) is respectfully requested.

Rejection of Claims 12 and 15 under 35 USC 103(a) over Schaeffer et al. (U.S. Patent Application 2002/0107641) in view of Buechler et al. (U.S. 6,830,731)

Reversal of the rejection of claims 12 and 15 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application 2002/0107641 issued to Schaeffer in view of U.S. Patent 6,830,731 issued to Buechler et al. is respectfully requested because the rejection makes crucial errors in interpreting the cited references. The rejection erroneously states that claims 12 and 15 are made unpatentable by Schaeffer in view of Buechler.

CLAIM 12

Dependent claim 12 is considered to be patentable based on its dependence on claims 1 and 3. Claim 12 is also considered to be patentable because Schaeffer and Buechler, individually or in combination, neither show nor suggest the combination of features of claim 12 in which "one of said plurality of validation preconditions corresponds to an **elapsed time period** to wait before comparing said laboratory test result with said

expected test result, said elapsed time period being a time period following initiation of said laboratory test."

Neither Schaeffer nor Buechler alone or together, show or suggest a user interface for "receiving" "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result". Schaeffer, as recognized in the Rejection, fails to show or suggest "one of said plurality of **validation preconditions** corresponds to an **elapsed time period** to wait before comparing said laboratory test result with said expected test result, said elapsed time period being a time period following initiation of said laboratory test". However, contrary, to the Rejection statement on page 7, Buechler in column 12 lines 32-39 merely states that timing of an assay test may be controlled. Buechler (with Schaeffer) fails to suggest employing "**user entered** data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions" including "an **elapsed time period** to wait before comparing said laboratory test result with said expected test result, said elapsed time period being a time period following initiation of said laboratory test" in "comparing said laboratory test result with said expected test result".

Further, employing the Buechler assay timing in Schaeffer results in a system using data mining approaches to better predict the pathogen encountered and to provide better medical practitioner guidance with respect to the undiagnosed patient based on the historical epidemiological data such as epidemiology profiles derived using timed assay tests, patient demographics, and similar symptoms and are used to suggest courses of treatment. Such a system fails to show or suggest a user interface for "receiving" "user

entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in **comparing** said laboratory test result **with** said **expected** test result and identifying a **first failure condition** in response to said laboratory test result failing to match said expected test result". Also, since Schaeffer and Buechler, alone or together, fail to recognize or address the specific problem of facilitating the operation of laboratory testing or of providing a system that "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2 lines 24-29), neither Schaeffer nor Buechler contain any motivation or other reason for incorporating the features of the claimed arrangement. Consequently, withdrawal of the rejection of claim 12 under 35 USC 103(a) is respectfully requested.

CLAIM 15

Dependent claim 15 is considered to be patentable based on its dependence on claim 1 for reasons given in connection with claims 1 and 8. Claim 15 is also considered to be patentable because Schaeffer and Buechler, individually or in combination, neither show nor suggest the combination of features of claim 15 including "an authorization processor for determining whether a user is authorized to override said failure condition and to inhibit override in response to a determination said user is unauthorized". Contrary to the Rejection statement on page 8, Buechler in column 9 lines 11-16 discusses user accessibility for purposes of changing fluorometer parameters and NOT to "inhibit override" of a determined "**failure condition**" in "response to a determination said user is unauthorized." Incorporating the identified feature in Buechler fails to show or suggest the claimed arrangement. Also, since Schaeffer and Buechler, alone or together, fail to recognize or address the specific problem of facilitating the operation of laboratory testing

or of providing a system that "improves upon this process by providing techniques that consider the results of earlier performed tests when entering results for later performed tests so that inconsistent or wrong results are not released to a physician for review" (Application page 2 lines 24-29), neither Schaeffer nor Buechler contain any motivation or other reason for incorporating the features of the claimed arrangement. Consequently, withdrawal of the rejection of claim 15 under 35 USC 103(a) is respectfully requested.

Rejection of Claim 16 under 35 USC 103(a) over Schaeffer et al. (U.S. Patent Application 2002/0107641) in view of Moskoff (U.S. 6,753,186)

Reversal of the rejection of claim 16 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application 2002/0107641 issued to Schaeffer in view of U.S. Patent 6,753,186 issued to Moskoff is respectfully requested because the rejection makes crucial errors in interpreting the cited references. The rejection erroneously states that claim 16 is made unpatentable by Schaeffer in view of Moskoff.

Dependent claim 16 is considered to be patentable based on its dependence on claim 1. Claim 16 is also considered to be patentable because Schaeffer and Buechler, individually or in combination, neither show nor suggest the combination of features of claim 16 in which "said result processor initiates generation of an alert message with a plurality of different warning severity message levels."

Neither Schaeffer nor Moskoff, alone or together, show or suggest a user interface for "receiving" "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition

in response to said laboratory test result failing to match said expected test result". Schaeffer, as recognized in the Rejection, fails to show or suggest "said result processor initiates generation of an alert message with a plurality of different warning severity message levels". Contrary, to the Rejection statement on page 9, Moskoff in column 14 line 55 to column 15 line 10 merely discusses water quality testing. Moskoff (with Schaeffer) fails to suggest employing "user entered data" "identifying a validation pre-condition" and "employing one or more user determined validation pre-conditions" in "comparing said laboratory test result with said expected test result" and initiating "generation of an alert message with a plurality of different warning severity message levels". Further Moskoff concerns water quality monitoring and is non-analogous art. One of ordinary skill in the art of laboratory equipment user interface systems would not be prompted to look to the field of water quality monitoring and treatment. Consequently, withdrawal of the Rejection of claim 16 under 35 USC 103(a) is respectfully requested.

VIII CONCLUSION

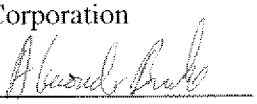
Schaeffer alone or in any combination with Peck, Buechler and Moskoff neither discloses nor suggests receiving "user entered data identifying a laboratory test result of a patient specimen culture and for receiving user entered data identifying an expected result of said laboratory test and data identifying a validation pre-condition" as recited in the present claimed invention. Additionally, Schaeffer alone or in any combination with Peck, Buechler and Moskoff neither disclose nor suggest "employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result" as recited in the present claimed invention. And finally, Schaeffer, alone or in any combination with Peck, Buechler and

Moskoff neither discloses nor suggests "a result processor for initiating generation of an alert message to a user indicating said first failure condition" as recited in the present claimed invention.

Accordingly it is respectfully submitted that the rejection of Claims 1– 25 should be reversed.

Respectfully submitted,
Siemens Medical Solutions Health Services Corporation

Date: July 11, 2006



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APPENDIX I - APPEALED CLAIMS

1. (Previously Presented) A system for processing information related to laboratory tests and results, comprising:

an interface processor for receiving user entered data identifying a laboratory test result of a patient specimen culture and for receiving user entered data identifying an expected result of said laboratory test and data identifying a validation pre-condition;

a validation processor for employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and identifying a first failure condition in response to said laboratory test result failing to match said expected test result; and

a result processor for initiating generation of an alert message to a user indicating said first failure condition.

2. (Original) A system according to claim 1, wherein said interface processor

further receives user entered data identifying at least one further laboratory test result of said patient and user entered data identifying at least one further expected laboratory test result of said at least one further laboratory test; and

wherein said validation processor compares said at least one further laboratory test result with said at least one further expected laboratory test result and identifies a second failure condition in response to said at least one further laboratory test result of said patient failing to match said at least one further expected laboratory test result; and

wherein said result processor initiates generation of an alert message to a user indicating said second failure condition.

3. (Previously Presented) A system according to claim 1, wherein said interface processor

further receives user entered data identifying a plurality of validation pre-conditions for validating said laboratory test of said patient;

wherein said validation processor identifies a second failure condition when at least one of said plurality of validation pre-conditions are not satisfied; and

wherein said result processor initiates generation of an alert message to a user indicating said second failure condition.

4. (Original) A system according to claim 1, wherein

said received user entered data identifying an expected result of said laboratory test comprises at least one of, (a) an identifier indicating a culture is resistant to a test compound, (b) an identifier indicating a culture is sensitive to a test compound, (c) an identifier indicating a positive test result and (d) an identifier indicating a negative test result.

5. (Original) A system according to claim 1, wherein

said received user entered data identifying an expected result of said laboratory test comprises a quantity identifier indicating presence of an approximate quantity of microbes per unit area of a culture.

6. (Original) A system according to claim 5, wherein

said quantity identifier identifies a qualitative range of said quantity of microbes per unit area, including at least one of, (a) an identifier indicating "few" and (b) an identifier indicating "many".

7. (Original) A system according to claim 5, wherein

said microbes comprise at least one of, (a) a bacteria, (b) a fungi, (c) a parasite and (d) a virus.

8. (Original) A system according to claim 1, wherein

said received user entered data identifying an expected result of said laboratory test identifies at least one of, (a) a count value of number of microbes present per unit area of a culture, (b) a color of a microbe indicator, (c) a color change of a microbe indicator.

9. (Previously Presented) A system according to claim 1, wherein

said received user entered data identifies a plurality of expected results of said laboratory test and said validation processor compares a plurality of laboratory test results with said plurality of expected results and identifies a failure condition in response to a predetermined condition if at least one of said plurality of laboratory test results fails to match a corresponding one of said plurality of expected results.

10. (Original) A system according to claim 1, wherein

said interface processor receives user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test,

said validation processor compares an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results and identifies a failure condition in response to said individual laboratory test result failing to match said corresponding expected test result; and

said result processor initiates generation of an alert message to a user indicating a failure condition of said individual test performed at a particular time stage of said different time stages.

11. (Previously Presented) A system according to claim 1, wherein

said result processor initiates generation of an alert message to a user in response to occurrence of said failure condition, said message at least one of, (a) prompting a user to initiate performance of another predetermined laboratory test, (b) informing a user of potential reasons for said failure condition, (c) prompting a user to repeat said laboratory test, (d) prompting a user with a user predetermined message and (e) identifying an expected result and actual result of said laboratory test.

12. (Original) A system according to claim 3, wherein

one of said plurality of validation preconditions corresponds to an elapsed time period to wait before comparing said laboratory test result with said expected test result, said elapsed time period being a time period following initiation of said laboratory test.

13. (Original) A system according to claim 1, wherein

said result processor initiates generation of an alert message to a user prompting a user to enter an override command indicating whether said failure condition is to be overridden.

14. (Original) A system according to claim 13, wherein

said result processor initiates storage of a record indicating said failure condition was overridden, in response to said user override command,

said record at least one of, (a) being accessible by an authorized person, (b) providing an audit trail indicating a person entering said override command and (c) being incorporated in a report identifying override command occurrences.

15. (Previously Presented) A system according to claim 13, including

an authorization processor for determining whether a user is authorized to override said failure condition and to inhibit override in response to a determination said user is unauthorized.

16. (Original) A system according to claim 1, wherein

said result processor initiates generation of an alert message with a plurality of different warning severity message levels.

17. (Previously Presented) A user interface system for use processing information related to laboratory tests and results, comprising:

a display processor for initiating generation of at least one display image including display elements for,

enabling a user to enter data identifying a laboratory test result of a patient specimen culture and to enter data identifying an expected result of said laboratory test and one or more validation pre-conditions, and for

displaying an alert message to a user indicating a failure condition derived by employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result and by determining a failure condition in response to said laboratory test result failing to match said expected test result.

18. (Original) A user interface system according to claim 17, wherein

said at least one display image includes display elements for enabling a user to enter data identifying an expected result of said laboratory test comprising at least one of, (a) an identifier indicating a culture is resistant to a test compound, (b) an identifier indicating a culture is sensitive to a test compound, (c) an identifier indicating a positive test result and (d) an identifier indicating a negative test result and (e) a quantity identifier indicating presence of an approximate quantity of microbes per unit area of a culture.

19. (Original) A user interface system according to claim 17, wherein

said at least one display image includes display elements for displaying an alert message to a user prompting a user to enter an override command indicating whether said failure condition is to be overridden.

20. (Previously Presented) A system for processing information related to laboratory tests and results, comprising:

an interface processor for receiving user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test;

a validation processor for employing one or more user determined validation pre-conditions in comparing an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results and identifies a failure condition in response to said individual laboratory test result failing to match said corresponding expected test result; and

a result processor for initiating generation of an alert message to a user indicating a failure condition of said individual test performed at a particular time stage of said different time stages.

21. (Previously Presented) A method for processing information related to laboratory tests and results, comprising the activities of:

receiving user entered data identifying a laboratory test result of a patient specimen culture;

receiving user entered data identifying an expected result of said laboratory test;

employing one or more user determined validation pre-conditions in comparing said laboratory test result with said expected test result;

identifying a failure condition in response to said laboratory test result failing to match said expected test result; and

initiating generation of an alert message to a user indicating said failure condition.

22. (Previously Presented) A method for processing information related to laboratory tests and results, comprising the activities of:

receiving user entered data identifying a plurality of results expected for a corresponding plurality of test results derived at different time stages of a laboratory test;

employing one or more user determined validation pre-conditions in comparing an individual result of said plurality of expected test results with a corresponding individual laboratory test result of said plurality of test results;

identifying a failure condition in response to said individual laboratory test result failing to match said corresponding expected test result; and

initiating generation of an alert message to a user indicating a failure condition of said individual test performed at a particular time stage of said different time stages.

23. (Previously Presented) A user interface system for processing information related to laboratory tests and results, comprising:

a display processor for initiating generation of at least one display image including display elements for,

enabling a user to enter data identifying an expected laboratory test result, a laboratory test result; at least one further expected laboratory test result, at least one further laboratory test result; and a plurality of validation pre-conditions for validating said first laboratory test, and for

displaying an alert message to a user indicating a failure condition derived by,

employing one or more user determined validation pre-conditions in comparing said expected laboratory test result with said laboratory test result

and identifying a first failure condition in response to said laboratory test result failing to match said expected laboratory test result;

comparing said at least one further laboratory test result with said at least one further expected laboratory test result and identifying a second failure condition in response to said at least one further laboratory test result failing to match said at least one further expected laboratory test result; and

determining that at least one of said plurality of validation pre-conditions are not satisfied.

24. (Previously Presented) A method for processing information related to laboratory tests and results, comprising:

a) receiving user entered data comprising:

an expected first laboratory test result of a first laboratory test requiring validation processing;

an actual first laboratory test result;

at least one further expected laboratory test result of at least one further laboratory test for validating said first laboratory test; and

at least one further actual laboratory test result of said at least one further laboratory test; and

a plurality of validation pre-conditions;

b) employing one or more user determined validation pre-conditions in comparing said expected first laboratory test result with said actual first laboratory test result and identifying a first failure condition in response to said expected first laboratory test result failing to match said actual first laboratory test result;

c) comparing said at least one further expected laboratory test result with said at least one further actual laboratory test result and identifying a second failure

condition in response to said at least one further expected laboratory test result failing to match said at least one further actual laboratory test result; and

d) identifying a third failure condition when said plurality of validation pre-conditions are not satisfied.

25. (Original) The method of Claim 24, further comprising the steps of initiating generation of an alert message to a user responsive to said first, second or third failure conditions.

APPENDIX II - EVIDENCE

Applicant does not rely on any additional evidence other than the arguments submitted hereinabove.

APPENDIX III - RELATED PROCEEDINGS

Applicant respectfully submits that there are no proceedings related to this appeal in which any decisions were rendered.

APPENDIX IV - TABLE OF CASES

1. *In re Howard*, 394 F. 2d 869, 157 USPQ 615, 616 (CCPA 1968)
2. 29 AM. Jur 2D Evidence S. 33 (1994)
3. *In re Ahlert*, 424 F. 2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970)
4. *In re Eynde*, 480 F. 2d 1364, 1370; 178 USPQ 470, 474 (CCPA 1973)
5. *In re Fine*, 5 USPQ 2d 1600, (Fed Cir. 1988)
6. ACS Hospital Systems Inc v. Montefiore Hospital, 221 USPQ 929,933 (Fed. Cir. 1984)
7. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (CCPA 1966)
8. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed.Cir. 1988), *cert. denied*, 488 U.S. 825 (1988)
9. *Ashland Oil Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 28, 293, 227 USPQ 657, 664 (Fed.Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986)
10. *In re Oetiker*, 977 F2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992)

APPENDIX V - LIST OF REFERENCES

U.S. Pat. No.	Issued Date	102(e) Date	Inventors
5,789,173	August 4, 1998		Peck et al.
6,830,731	December 14, 2004		Buechler et al.
6,753,186 B2	June 22, 2004		Moskoff

U.S. Pub. No.	Pub. Date	Inventors
2002/017641 A1	August 8, 2002	Schaeffer et al.

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